glenmark
A new way for a new world

DRUG MARKET WITHDRAWAL

IMIQUIMOD CREAM USP 5%
(0.25 g Sachet pack)
(NDC 68462-536-70)

December 30, 2024

Dear Pharmacy, Wholesale and Retail Customer:

This is to inform you that Glenmark is initiating a Market Withdrawal to the Retail level involving the following prescription product batches:

Sr. No.	NDC	Strength	Batch Number	Pack Size	Expiry
1	68462-536-70	5%	19230117	0.25 g Sachet pack	December - 2024
2	68462-536-70	5%	19230225	0.25 g Sachet pack	December - 2024
3	68462-536-70	5%	19230447	0.25 g Sachet pack	January - 2025
4	68462-536-70	5%	19230562	0.25 g Sachet pack	January - 2025
5	68462-536-70	5%	19230688	0.25 g Sachet pack	January - 2025
6	68462-536-70	5%	19230766	0.25 g Sachet pack	January - 2025
7	68462-536-70	5%	19231268	0.25 g Sachet pack	February - 2025
8	68462-536-70	5%	19231312	0.25 g Sachet pack	March - 2025
9	68462-536-70	5%	19231503	0.25 g Sachet pack	March - 2025
10	68462-536-70	5%	19231588	0.25 g Sachet pack	March - 2025
11	68462-536-70	5%	19232359	0.25 g Sachet pack	May - 2025
12	68462-536-70	5%	19232558	0.25 g Sachet pack	May - 2025
13	68462-536-70	5%	19233809	0.25 g Sachet pack	August - 2025
14	68462-536-70	5%	19233971	0.25 g Sachet pack	September - 2025
15	68462-536-70	5%	19234256	0.25 g Sachet pack	September - 2025
16	68462-536-70	5%	19234436	0.25 g Sachet pack	October - 2025
17	68462-536-70	5%	19234677	0.25 g Sachet pack	October - 2025
18	68462-536-70	5%	19234851	0.25 g Sachet pack	November - 2025
19	68462-536-70	5%	19235006	0.25 g Sachet pack	November - 2025
20	68462-536-70	5%	19240226	0.25 g Sachet pack	December - 2025

The Market withdrawal to the ***retail level*** of the above identified product batches of Imiquimod Cream USP 5% has been initiated by Glenmark out of an abundance of precaution because an

Glenmark Pharmaceuticals Inc. USA 750 Corporate Drive, Mahwah, NJ 07430
T: 1 201 684 8000 F: 1 201 831 0080 www.glenmarkpharma.com/usa

increasing trend of assay result is observed in product Imiquimod Cream USP 5%, Batch # 19230562 during long-term stability study. This batch was charged on stability study as an annual stability monitoring batch for the year 2023. The assay result observed at 18 Months long-term (25°C/60% RH) stability interval is 107% against the specification of NLT 90% and NMT 110% of the labeled amount of Imiquimod. The shelf life of the product is 24 months with the expiry of this Batch # 19230562 as January 2025.

Glenmark changed the laminate (primary packing material) from laminate "PET/ALU/PET/LDPE 4-layer laminate" to alternate new laminate "PAPER/PE/ALU/SURLYN 4-layer laminate". Upon receipt of PAS approval on November 03, 2021, the change was implemented in February 2022 effective from Batch # 19220797.

The Batch # 19230562 (Manufacturing date: February 2023) was packed with the new laminate PAPER/PE/ALU/SURLYN 4-layer. As of today, in addition to aforementioned batch # 19230562, two batches were charged on stability with the new laminate. Both these batches have completed the stability study till the shelf life of 24 months. Assay results of both the batches at 24 months (shelf life) time point comply with the specification however reported at the higher side of the specification limit.

Since all three batches on stability study with new laminate have shown an increasing trend in Assay results and are nearer to the maximum specification limit of 110% towards the end of shelf life, as an abundance of caution, Glenmark proposes market withdrawal of all the batches of Imiquimod Cream USP 5% that are within-shelf life and packed with new laminate PAPER/PE/ALU/SURLYN 4-layer laminate.

Please see details of product batches listed in above table and refer enclosed product labels for ease in identifying the product.

Please examine your inventory and if you have any inventory available for the batches specified in the above table, you should quarantine such product immediately and not dispense any further product from these lots. Glenmark Pharmaceuticals Inc., USA initiated shipment of this product on 28 February, 2023.

In addition, if you are a wholesaler/ distributor, who has further distributed this product, please identify those retail customers and notify them at once of this Market Withdrawal. Your notification to your retail customers may be enhanced by including a copy of this market withdrawal notification letter. Again, this market withdrawal should be carried out to the retail level only. Because this is not a consumer level market withdrawal, notice to the consumer level is not required.

Glenmark Pharmaceuticals Inc. USA 750 Corporate Drive, Mahwah, NJ 07430
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We are requesting the batches specified in the above table to be returned to Inmar Rx Solutions (address below) using the Postage Paid Product Return label that was provided in your Market Withdrawal Return Packet.

Inmar Rx Solutions
3845 Grand Lakes Way
Grand Prairie, TX 75050

Please complete and return the enclosed response form preferably within 72 hours of receipt of this notification. Please either fax your response to 817-868-5362 or email to Rxrecalls@Inmar.com.

If you have any questions regarding your market withdrawal return please contact Inmar at 877-560-5377

Inmar office hours are Monday through Friday, from 9 am to 5 pm EST.

This market withdrawal is being made with the knowledge of the Food and Drug Administration.

Thank you for your cooperation,

Sincerely,

GLENMARK PHARMACEUTICALS INC., USA

Thomas Callaghan

Executive Director - Regulatory Affairs, North America

US Agent for Glenmark Pharmaceuticals Limited

Enclosure(s):

Product Labels

Market Withdrawal Return Response Form

Glenmark Pharmaceuticals Inc. USA 750 Corporate Drive, Mahwah, NJ 07430
T: 1 201 684 8000 F: 1 201 831 0080 www.glenmarkpharma.com/usa

FOIL WIDTH : 192 MM
1 X0.25GM STRIP SIZE : 32MM X 54MM
3 X 0.25GM STRIP SIZE : 96MM X 54 MM

Sachet size: 32 mm x 54 mm
foil width : 192 mm

Imiquimod Cream USP, 5%
Not for Ophthalmic Use.
For Dermatologic Use Only.
Contains
1 Application
Discard unused packet
Net Wt. 0.25 g
Glenmark

Imiquimod Cream USP, 5%
Not for Ophthalmic Use.
For Dermatologic Use Only.
Contains
1 Application
Discard unused packet
Net Wt. 0.25 g
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Imiquimod Cream USP, 5%
Not for Ophthalmic Use.
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Contains
1 Application
Discard unused packet
Net Wt. 0.25 g
Glenmark

See Package Insert for Dosage Information
Store at 4°C to 25°C (39°F to 77°F).
Avoid freezing.
Manufactured for:
Glenmark Pharmaceuticals Inc., USA
Mahwah, NJ 07430
Product of India
GO/DRUGS/648
03/21
PE58651 0321-1
N 3 68462 53670 4
Questions? 1 (888) 721-7115
www.glenmarkpharma-us.com

See Package Insert for Dosage Information
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1 X0.25GM STRIP SIZE: 32MM X 54MM

3 X 0.25GM STRIP SIZE : 96MM X 54 MM

FONT TYPE: SWITZERLAND CONDENSED
MINIMUM FONT SIZE: 5.2 PT

DATE: 26-03-2021
VERSION: 01

GLENMARK PHARMACEUTICALS LTD.	DATE:	PANTONE SHADE NO: Black, 186 C, 2945 C, NON PRINTING COLOUR	
PRODUCT NAME: IMIQUIMOD CREAM ITEM CODE: PE58651 VERSION: 0321-1	PKG. DEV.:	Item code, Version, Consistency of Design, overprint area, Pack size, Dimensions & Layout	Dimple Pradhan — Digitally signed by Dimple Pradhan Date: 2021.04.23 11:32:28 +05'30'
PHARMACODE: NA	RA	Regulatory Text	
COUNTRY: USA	PRODUCTION:	Machine Suitability	Siddesh Dongrekar 91200296 Manager Production
LOCATION: GOA PACK : SACHET	QA:	Entire Text	Vikram Desai (90033648) Sr. Officer QA — Digitally signed by Vikram Desai (90033648) Sr. Officer QA Date: 2021.04.29 14:46:27 +05'30'
ACTUAL SIZE: FOIL WIDTH: 192 mm	REMARKS:		
SPECIFICATION:			

FCPDC001/01.00

May Breedlove — Digitally signed by May Breedlove Date: 2021.04.08 10:58:59 -04'00'

Carole Capella — Digitally signed by Carole Capella Date: 2021.04.08 11:21:08 -04'00'

Kristin DiStefano — Digitally signed by Kristin DiStefano Date: 2021.04.08 11:44:15 -04'00'

Carole Capella
Digitally signed by Carole Capella
Date: 2021.04.08 11:21:39 -04'00'

Kristin DiStefano
Digitally signed by Kristin DiStefano
Date: 2021.04.08 11:45:06 -04'00'

SAME SIZE ARTWORK
SIZE: 105 x 18 x 60 mm
(Reverse Tuck-in Flap)

FONT TYPE: SWITZERLAND CONDENSED
MINIMUM FONT SIZE: 6 PT

DATE: 26-03-2021
VERSION: 01

GLENMARK PHARMACEUTICALS LTD.			
PRODUCT NAME: IMIQUIMOD CREAM	DATE:	PANTONE SHADE NO: Black, 186 C, 2945 C, NON PRINTING COLOUR	
ITEM CODE: PE58652 VERSION: 0321-1	PKG. DEV.:	Item code, Version, Consistency of Design, overprint area, Pack size, Dimensions & Layout	Dimple Pradhan Digitally signed by Dimple Pradhan Date: 2021.04.23 11:39:21 +05'30'
PHARMACODE: 58652	RA	Regulatory Text	
COUNTRY: USA	PRODUCTION:	Machine Suitability	Siddesh Dongrekar 91200296 Manager Production Digitally signed by Siddesh Dongrekar 91200296 Manager Production Date: 2021.04.23 14:00:43 +05'30'
LOCATION: GOA	QA:	Entire Text	Vikram Desai (90033648) Sr. Officer QA Digitally signed by Vikram Desai (90033648) Sr. Officer QA Date: 2021.04.29 14:45:37 +05'30'
PACK : CARTON	REMARKS:		
ACTUAL SIZE: 105 mm x 18 mm x 60 mm			
SPECIFICATION: 300 GSM ITC Cyber XL with Aqua varnish except for the area marked			

FCPDC001/01.00

*Sections or subsections omitted from the Full Prescribing Information are not listed.

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the topical treatment of clinically typical, nonhyperkeratotic, the face or scalp in immunocompetent adults.

reatment of external genital and perianal warts/condyloma acuminata

d in children ages 2 to 12 years with molluscum contagiosum and fficacy *[see Use in Specific Populations (8.4)]*.

Cream in immunosuppressed patients have not been established.
th caution in patients with pre-existing autoimmune conditions.
Cream have not been established for patients with Basal Cell Nevus im.

imod Cream is different for each indication.
:, or intravaginal use.

2 times per week for a full 16 weeks to a defined treatment area on urrently). The treatment area is defined as one contiguous area of m) on the face (e.g. forehead or one cheek) or on the scalp. Examples dules are Monday and Thursday, or Tuesday and Friday. Imiquimod e treatment area and rubbed in until the cream is no longer visible. id Cream should be applied to the contiguous treatment area at each **id be applied prior to normal sleeping hours and left on the skin ich time the cream should be removed by washing the area with** should demonstrate the proper application technique to maximize apy.
sh their hands before and after applying Imiquimod Cream. Before ld wash the treatment area with mild soap and water and allow the nutes).
ls should be avoided.
area are common *[see Adverse Reactions (6.1, 6.5)]*. A rest period ed by the patient's discomfort or severity of the local skin reaction. **ld not be extended beyond 16 weeks due to missed doses or rest** not be adequately assessed until resolution of local skin reactions. ent should be carefully re-evaluated and management reconsidered.
gle-use packets, with 24 packets supplied per box. **Patients should kets for the 16-week treatment period**. Unused packets should be uld be discarded and not reused.

3 times per week to external genital/perianal warts. Imiquimod Cream s total clearance of the genital/perianal warts or for a maximum of 16 application schedules are: Monday, Wednesday, Friday or Tuesday, **am should be applied prior to normal sleeping hours and left on ch time the cream should be removed by washing the area with** should demonstrate the proper application technique to maximize apy.
their hands before and after applying Imiquimod Cream.
uld be applied to the wart area and rubbed in until the cream is no uld not be occluded. Following the treatment period the cream should rea with mild soap and water.
site are common *[see Adverse Reactions (6.3, 6.5)]*. A rest period ed by the patient's discomfort or severity of the local skin reaction. ction subsides. Non-occlusive dressings such as cotton gauze or management of skin reactions.
gle-use packets which contain sufficient cream to cover a wart area ounts of cream should be avoided.

3
lied in single-use packets, each of which contains 250 mg of the quimod, USP. Imiquimod Cream USP, 5% is supplied in boxes of

including skin weeping or erosion can occur after few applications e an interruption of dosing *[see Dosage and Administration (2) and* ream has the potential to exacerbate inflammatory conditions of the ost disease.
of the female external genitalia can lead to severe vulvar swelling. rinary retention. Dosing should be interrupted or discontinued for

is not recommended until the skin is completely healed from any intra-anal human papilloma viral disease.

6 ADVERSE REACTIONS
Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

6.1 Clinical Trials Experience: Actinic Keratosis
The data described below reflect exposure to Imiquimod Cream or vehicle in 436 subjects enrolled in two double-blind, vehicle-controlled studies. Subjects applied Imiquimod Cream or vehicle to a 25 cm^2 contiguous treatment area on the face or scalp 2 times per week for 16 weeks.

Table 1: Selected Adverse Reactions Occurring in >1% of Imiquimod -Treated Subjects and at a Greater Frequency than with Vehicle in the Combined Studies (Actinic Keratosis)

Preferred Term	Imiquimod Cream (n=215)	Vehicle (n=221)
Application Site Reaction	71 (33%)	32 (14%)
Upper Resp Tract Infection	33 (15%)	27 (12%)
Sinusitis	16 (7%)	14 (6%)
Headache	11 (5%)	7 (3%)
Carcinoma Squamous	8 (4%)	5 (2%)
Diarrhea	6 (3%)	2 (1%)
Eczema	4 (2%)	3 (1%)
Back Pain	3 (1%)	2 (1%)
Fatigue	3 (1%)	2 (1%)
Fibrillation Atrial	3 (1%)	2 (1%)
Infection Viral	3 (1%)	2 (1%)
Dizziness	3 (1%)	1 (<1%)
Vomiting	3 (1%)	1 (<1%)
Urinary Tract Infection	3 (1%)	1 (<1%)
Fever	3 (1%)	0 (0%)
Rigors	3 (1%)	0 (0%)
Alopecia	3 (1%)	0 (0%)

Table 2: Application Site Reactions Reported by > 1% of Imiquimod -Treated Subjects and at a Greater Frequency than with Vehicle in the Combined Studies (Actinic Keratosis)

Included Term	Imiquimod Cream n=215	Vehicle n=221
Itching	44 (20%)	17 (8%)
Burning	13 (6%)	4 (2%)
Bleeding	7 (3%)	1 (<1%)
Stinging	6 (3%)	2 (1%)
Pain	6 (3%)	2 (1%)
Induration	5 (2%)	3 (1%)
Tenderness	4 (2%)	3 (1%)
Irritation	4 (2%)	0 (0%)

Local skin reactions were collected independently of the adverse reaction "application site reaction" in an effort to provide a better picture of the specific types of local reactions that might be seen.
The most frequently reported local skin reactions were erythema, flaking/scaling/dryness, and scabbing/crusting.
The prevalence and severity of local skin reactions that occurred during controlled studies are shown in the following table.

Table 3: Local Skin Reactions in the Treatment Area as Assessed by the Investigator (Actinic Keratosis)

	Imiquimod Cream (n=215)		Vehicle (n=220)	
	All Grades*	Severe	All Grades*	Severe
Erythema	209 (97%)	38 (18%)	206 (93%)	5 (2%)
Flaking/Scaling/Dryness	199 (93%)	16 (7%)	199 (91%)	7 (3%)
Scabbing/Crusting	169 (79%)	18 (8%)	92 (42%)	4 (2%)
Edema	106 (49%)	0 (0%)	22 (10%)	0 (0%)
Erosion/Ulceration	103 (48%)	5 (2%)	20 (9%)	0 (0%)
Weeping/Exudate	45 (22%)	0 (0%)	3 (1%)	0 (0%)
Vesicles	19 (9%)	0 (0%)	2 (1%)	0 (0%)

*Mild, Moderate, or Severe

The adverse reactions that most frequently resulted in clinical intervention (e.g., rest periods, withdrawal from study) were local skin and application site reactions. Overall, in the clinical studies, 2% (5/215) of subjects discontinued for local skin/application site reactions. Of the 215 subjects treated, 35 subjects (16%) on Imiquimod Cream and 3 of 220 subjects (1%) on vehicle cream had at least one rest period. Of these Imiquimod Cream subjects, 32 (91%) resumed therapy after a rest period.
In the AK studies, 22 of 678 (3.2%) of Imiquimod -treated subjects developed treatment site infections that required a rest period off Imiquimod Cream and were treated with antibiotics (19 with oral and 3 with topical). Of the 206 Imiquimod subjects with both baseline and 8 week post-treatment scoring assessments, 6

clinical trials are shown in the following table.

Table 4: Local Skin Reactions in the Treatment Area as As (External Genital Warts)

	Imiquimod Cream				
	Females		Males		Fe
	n=114		n=156		n
	All Grades*	Severe	All Grades*	Severe	All Grades
Erythema	74 (65%)	4 (4%)	90 (58%)	6 (4%)	21 (21%
Erosion	35 (31%)	1 (1%)	47 (30%)	2 (1%)	8 (8%)
Excoriation/ Flaking	21 (18%)	0 (0%)	40 (26%)	1 (1%)	8 (8%)
Edema	20 (18%)	1 (1%)	19 (12%)	0 (0%)	5 (5%)
Scabbing	4 (4%)	0 (0%)	20 (13%)	0 (0%)	0 (0%)
Induration	6 (5%)	0 (0%)	11 (7%)	0 (0%)	2 (2%)
Ulceration	9 (8%)	3 (3%)	7 (4%)	0 (0%)	1 (1%)
Vesicles	3 (3%)	0 (0%)	3 (2%)	0 (0%)	0 (0%)

*Mild, Moderate, or Severe

Remote site skin reactions were also reported. The severe remote site were erythema (3%), ulceration (2%), and edema (1%); and for m edema, induration, and excoriation/flaking (each 1%).
Selected adverse reactions judged to be probably or possibly related to

Table 5: Selected Treatment Related Reactions (Ext

	Females	
	Imiquimod Cream	Vehicle
Application Site Disorders:		
Application Site Reactions	n=117	n=103
Wart Site:		
Itching	38 (32%)	21 (20%)
Burning	30 (26%)	12 (12%)
Pain	9 (8%)	2 (2%)
Soreness	3 (3%)	0 (0%)
Fungal Infection*	13 (11%)	3 (3%)
Systemic Reactions:		
Headache	5 (4%)	3 (3%)
Influenza-like symptoms	4 (3%)	2 (2%)
Myalgia	1 (1%)	0 (0%)

*Incidences reported without regard to causality with Imiquimod Cre

Adverse reactions judged to be possibly or probably related to Imiqu than 1% of subjects included:

Application Site Disorders: burning, hypopigmentation, irritation, itch stinging, tenderness

Remote Site Reactions: bleeding, burning, itching, pain, tenderness

Body as a Whole: fatigue, fever, influenza-like symptoms

Central and Peripheral Nervous System Disorders: headache

Gastro-Intestinal System Disorders: diarrhea

Musculo-Skeletal System Disorders: myalgia

6.4 Clinical Trials Experience: Dermal Safety Studies
Provocative repeat insult patch test studies involving induction and cha that Imiquimod Cream causes photoallergenicity or contact sensitizatior irritancy testing revealed the potential for Imiquimod Cream to cause irr were reported in the clinical studies *[see Adverse Reactions (6)]*.

6.5 Postmarketing Experience
The following adverse reactions have been identified during post-approv these reactions are reported voluntarily from a population of uncerta reliably estimate their frequency or establish a causal relationship to

Application Site Disorders: tingling at the application site.

Body as a Whole: angioedema.

Cardiovascular: capillary leak syndrome, cardiac failure, cardiomyopa (tachycardia, atrial fibrillation, palpitations), chest pain, ischemia, my

Endocrine: thyroiditis.

Gastro-Intestinal System Disorders: abdominal pain.

Hematological: decreases in red cell, white cell and platelet counts (inc purpura), lymphoma.

Hepatic: abnormal liver function.

Infections and Infestations: herpes simplex.

8. In Study 1, the complete clearance rate was 24% (52/217) in the
ith 26% (28/106) in the vehicle group. In Study 2, the clearance rates
d Cream group compared with 28% (35/126) in the vehicle group.
fficacy.

ults, the most frequently reported adverse reaction from 2 studies in
n was application site reaction. Adverse events which occurred more
jects compared with vehicle-treated subjects generally resembled
proved for adults and also included otitis media (5% Imiquimod vs.
niquimod vs. 2% vehicle).

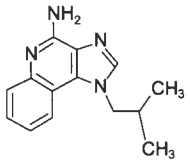
ported local skin reaction. Severe local skin reactions reported by
ediatric studies included erythema (28%), edema (8%), scabbing/
rosion (2%) and weeping/exudate (2%).

oss the affected skin of 22 subjects aged 2 to 12 years with extensive
l body surface area was observed after single and multiple doses at
per week for 4 weeks. The investigator determined the dose applied,
sed on the size of the treatment area and the subject's weight. The
ncentrations at the end of week 4 was between 0.26 and 1.06 ng/
was administered 2 packets of study drug per dose, had a C_{max} of
ildren aged 2 to 5 years received doses of 12.5 mg (one packet) or
d had median multiple-dose peak serum drug levels of approximately
en aged 6 to 12 years received doses of 12.5 mg, 25 mg, or 37.5 mg
iple dose serum drug levels of approximately 0.1, 0.15, or 0.3 ng/
cts with evaluable laboratory assessments, the median WBC count
an absolute neutrophil count decreased by $1.42*10^9$/L.

quimod Cream in the AK clinical studies, 127 subjects (59%) were
(28%) were 75 years and older. No overall differences in safety or
these subjects and younger subjects. No other clinical experience
s between the elderly and younger subjects, but greater sensitivity
uled out.

m could result in an increased incidence of severe local skin reactions
ic reactions.
vent reported following multiple oral imiquimod doses of >200 mg
>16 packets) was hypotension, which resolved following oral or

response modifier for topical administration. Each gram contains 50
oil-in-water vanishing cream base consisting of benzyl alcohol, cetyl
hylparaben, polysorbate 60, propylparaben, purified water, sorbitan
petrolatum and xanthan gum.
ethylpropyl)-1 H-imidazo[4,5-c]quinolin-4-amine. Imiquimod, USP
nd a molecular weight of 240.3 g/mol. Its structural formula is:



od Cream in treating AK is unknown.

paring Imiquimod Cream to vehicle, increases from baseline in week
CD3, CD4, CD8, CD11c, and CD68 for Imiquimod Cream treated
nce of these findings is unknown.

vity in cell culture. A study in 22 subjects with genital/perianal warts
icle shows that Imiquimod Cream induces mRNA encoding cytokines
ent site. In addition HPVL1 mRNA and HPV DNA are significantly
ver, the clinical relevance of these findings is unknown.

cross the affected skin of 58 subjects with AK was observed with a
week for 16 weeks. Mean peak serum drug concentrations at the end
.2, and 3.5 ng/mL for the applications to face (12.5 mg imiquimod, 1
ackets) and hands/arms (75 mg, 6 packets), respectively.

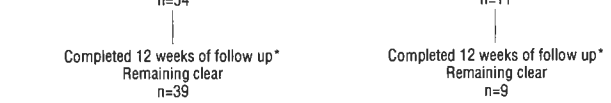
od Concentration in Adults Following Administration of the Dose During Week 16 (Actinic Keratosis)

plied	Mean peak serum imiquimod concentration [C_{max}]
	0.1 ng/mL
	0.2 ng/mL
	3.5 ng/mL

controlled when more than one packet was used. Dose proportion-
pears that systemic exposure may be more dependent on surface
plied dose. The apparent half-life was approximately 10 times
hour apparent half-life seen following subcutaneous dosing, sug-
n the skin. Mean urinary recoveries of imiquimod and metabolites
e applied dose in the group using 75 mg (6 packets) for males and
lications per week for 16 weeks.

vas observed across the affected skin of 12 subjects with genital/
of 4.6 mg. Mean peak drug concentration of approximately 0.4 ng/
urinary recoveries of imiquimod and metabolites combined over the
d as percent of the estimated applied dose, were 0.11 and 2.41% in

Impairment of Fertility
y study, imiquimod was administered to Wistar rats on a 2X/week
g/day) dosing schedule for 24 months. No treatment related tumors
icity study up to the highest doses tested in this study of 6 mg/kg
7X MRHD based on weekly AUC comparisons), 4 mg/kg administered
ed on weekly AUC comparisons) or 3 mg/kg administered 7X/week
based on weekly AUC comparisons).
dy, imiquimod cream (up to 5 mg/kg/application imiquimod or 0.3%
e backs of mice 3X/week for 24 months. A statistically significant
omas and carcinomas was noted in high dose male mice compared
based on weekly AUC comparisons). An increased number of skin
ream control group animals at the treated site only. The quantitative
ed in the dermal mouse carcinogenicity study is the same as the
eam, minus the active moiety (imiquimod).
genicity study, the median time to onset of skin tumor formation was
chronic topical dosing (3X/week; 40 weeks of treatment followed by
rent exposure to UV radiation (5 days per week) with the Imiquimod
fect on tumor development beyond the vehicle effect was noted with
miquimod, to the vehicle cream.
utagenic or clastogenic potential based on the results of five in vitro



*The other subjects were either lost to follow-up or experienced recurrences.

Data on complete clearance are listed in the table below. The median time to complete wart clearance was 10 weeks.

Table 8: Complete Clearance Rates (External Genital Warts)- Study EGW1

Treatment	Subjects with Complete Clearance of Warts	Subjects Without Follow-up	Subjects with Warts Remaining at Week 16
Overall			
Imiquimod Cream (n=109)	54 (50%)	19 (17%)	36 (33%)
Vehicle (n=100)	11 (11%)	27 (27%)	62 (62%)
Females			
Imiquimod Cream (n=46)	33 (72%)	5 (11%)	8 (17%)
Vehicle (n=40)	8 (20%)	13 (33%)	19 (48%)
Males			
Imiquimod Cream (n=63)	21 (33%)	14 (22%)	28 (44%)
Vehicle (n=60)	3 (5%)	14 (23%)	43 (72%)

16 HOW SUPPLIED/STORAGE AND HANDLING

Imiquimod Cream USP, 5% is supplied in single-use packets, which contain 250 mg of the cream. Available as: Box of 24 packets NDC 68462-536-70. Store at 4°C to 25°C (39°F to 77°F).

Avoid freezing.

Keep out of reach of children.

17 PATIENT COUNSELING INFORMATION

See FDA-Approved Patient Labeling

17.1 General Information: All Indications

Imiquimod Cream should be used as directed by a physician *[see Dosage and Administration (2)]*. Imiquimod Cream is for external use only. Contact with the eyes, lips and nostrils should be avoided *[see Indications and Usage (1) and Dosage and Administration (2)]*. The treatment area should not be bandaged or otherwise occluded. Partially-used packets should be discarded and not reused. The prescriber should demonstrate the proper application technique to maximize the benefit of Imiquimod Cream therapy.

It is recommended that patients wash their hands before and after applying Imiquimod cream.

17.2 Local Skin Reactions: All Indications

Patients may experience local skin reactions during treatment with Imiquimod Cream (even with normal dosing). Potential local skin reactions include erythema, edema, vesicles, erosions/ulcerations, weeping/exudate, flaking/scaling/dryness, and scabbing/crusting. These reactions can range from mild to severe in intensity and may extend beyond the application site onto the surrounding skin. Patients may also experience application site reactions such as itching and/or burning *[see Adverse Reactions (6)]*.

Local skin reactions may be of such intensity that patients may require rest periods from treatment. Treatment with Imiquimod Cream can be resumed after the skin reaction has subsided, as determined by the physician. Patients should contact their physician promptly if they experience any sign or symptom at the application site that restricts or prohibits their daily activity or makes continued application of the cream difficult.

Because of local skin reactions, during treatment and until healed, the treatment area is likely to appear noticeably different from normal skin. Localized hypopigmentation and hyperpigmentation have been reported following use of Imiquimod Cream. These skin color changes may be permanent in some patients.

17.3 Systemic Reactions: All Indications

Patients may experience flu-like systemic signs and symptoms during treatment with Imiquimod Cream (even with normal dosing). Systemic signs and symptoms may include malaise, fever, nausea, myalgias and rigors *[see Adverse Reactions (6)]*. An interruption of dosing should be considered.

17.4 Patients Being Treated for Actinic Keratosis (AK)

Dosing is 2 times per week for a full 16 weeks, unless otherwise directed by the physician. However, the treatment period should not be extended beyond 16 weeks due to missed doses or rest periods *[see Dosage and Administration (2.1)]*.

It is recommended that the treatment area be washed with mild soap and water 8 hours following Imiquimod Cream application.

Most patients using Imiquimod Cream for the treatment of AK experience erythema, flaking/scaling/dryness and scabbing/crusting at the application site with normal dosing *[see Adverse Reactions (6.1)]*.

Use of sunscreen is encouraged, and patients should minimize or avoid exposure to natural or artificial sunlight (tanning beds or UVA/B treatment) while using Imiquimod Cream *[see Warnings and Precautions (5.3)]*.

Sub-clinical AK lesions may become apparent in the treatment area during treatment and may subsequently resolve *[see Clinical Studies (14.1)]*.

17.6 Patients Being Treated for External Genital Warts

Dosing is 3 times per week to external genital/perianal warts. Imiquimod Cream treatment should continue until there is total clearance of the genital/perianal warts or for a maximum of 16 weeks.

It is recommended that the treatment area be washed with mild soap and water 6 to 10 hours following Imiquimod Cream application.

It is common for patients to experience local skin reactions such as erythema, erosion, excoriation/flaking, and edema at the site of application or surrounding areas. Most skin reactions are mild to moderate.

Sexual (genital, anal, oral) contact should be avoided while Imiquimod Cream is on the skin. Application of Imiquimod Cream in the vagina is considered internal and should be avoided. Female patients should take special care if applying the cream at the opening of the vagina because local skin reactions on the delicate moist surfaces can result in pain or severe swelling, and may cause difficulty in passing urine or inability to urinate.

Uncircumcised males treating warts under the foreskin should retract the foreskin and clean the area daily.

New warts may develop during therapy, as Imiquimod Cream is not a cure.

The effect of Imiquimod Cream on the transmission of genital/perianal warts is unknown.

Imiquimod Cream may weaken condoms and vaginal diaphragms, therefore concurrent use is not recommended.

Should severe local skin reaction occur, the cream should be removed by washing the treatment area with mild soap and water.

Rx Only

Manufactured by:
Glenmark Pharmaceuticals Limited
Colvale – Bardez, Goa 403 513, India

Manufactured for:
glenmark
Glenmark Pharmaceuticals Inc., USA
Mahwah, NJ 07430

Questions? 1 (888) 721–7115

www.glenmarkpharma-us.com

March 2021

Patient Information

- Wash the area where the cream will be applied with mild soap and w
warts under their penis foreskin must pull their foreskin back and
clean the area daily during treatment.
- Allow the area to dry for at least 10 minutes.
- Wash your hands.
- Open a new packet of Imiquimod Cream.
- Apply a thin layer of Imiquimod Cream only to the affected area.
than is needed to cover the affected area.
- Rub the cream into your skin until you cannot see the Imiquimo
Cream, wash your hands well.
- Leave the cream on the treated area for the amount of time your hea
of time that Imiquimod Cream is left on the skin is different for
Cream is used to treat. **Do not** take a bath or get the treated area
- After the right amount of time has passed, wash the treated area
- If you get Imiquimod Cream in your mouth or in your eyes, rinse

What should I avoid while using Imiquimod Cream?

- Do not cover the treated area with bandages or other closed dres
- Do not use sunlamps or tanning beds, and avoid sunlight as muc
Imiquimod Cream. Use sunscreen and wear protective clothing if
- Do not have sexual contact including genital, anal, or oral sex when
or the skin around your anus. Imiquimod Cream may weaken con
means they may not work as well to prevent pregnancy.

What are the possible side effects of Imiquimod Cream?

Imiquimod Cream may cause serious side effects including:

- **Local skin reactions**, including:
  - skin drainage (weeping)
  - ulcers
  - severe swelling near the vagina. This may lead to pain or trou
to be able to urinate. Female patients should take special care
the opening of the vagina.
- **Flu-like symptoms:** tiredness, fever, nausea, muscle pain and ch

Tell your healthcare provider right away if you have any of the sym

The most common side effects of Imiquimod Cream include:

- itching
- burning
- redness
- flaking and scaling
- dryness
- scabbing and crusting
- swelling
- skin that become
- sores, blisters, o
- changes in skin c

Tell your healthcare provider if you have any side effect that bothers
These are not all the possible side effects of Imiquimod Cream. For m
provider or pharmacist.

Call your doctor for medical advice about side effects. You may report si

How do I store Imiquimod Cream?

- Store imiquimod cream at 4°C to 25°C (39°F to 77°F).
- Do not freeze.
- Safely throw away unused imiquimod cream or partially used im
not need.

Keep Imiquimod Cream and all medicines out of the reach of child

General information about the safe and effective use of imiquimod

Medicines are sometimes prescribed for purposes other than those list
Do not use Imiquimod Cream for a condition for which it was not presc
to other people, even if they have the same symptoms you have. It m

This Patient Information leaflet summarizes the most important inf
If you would like more information, talk with your healthcare provid
healthcare provider for information about Imiquimod Cream that is wri

What are the ingredients in imiquimod cream?

Active ingredient: imiquimod, USP

Inactive ingredients: benzyl alcohol, cetyl alcohol, glycerin, isostearic
propylparaben, purified water, sorbitan monostearate, stearyl alcohol,

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March 2021

Glenmark
A new way for a new world

MARKET WITHDRAWAL RETURN RESPONSE FORM

IMIQUIMOD CREAM USP 5%, 0.25 g Sachet pack
NDC 68462-536-70
Retail Level
12/30/2024

Please fill out this form completely. By doing so, this will acknowledge that you have read and understand the withdrawal instructions and have taken the appropriate action.

Customer Name:	DEA#:

DEA # is required, if it is not provided, the processing of your form will be delayed.

Address: _____

City:	State:	Zip:

Contact Name (Please Print): _____

Telephone#:	Email:

Contact Signature:	Date:

DEBIT MEMO# (If unsure, leave blank): _____

Wholesaler Information if not directly purchased from Glenmark Pharmaceuticals Inc.:

Wholesaler Name:	DEA#:	
City:	State:	Zip:

I have checked my stock and communicated to my customers at the appropriate level:

☐ I confirm that all locations that received the impacted products have been notified to the Retail level _____(Initial and date)

☐ I do not have any stock of the market withdrawn items. **OR**

☐ I have quarantined and listed in the box below the quantity of market withdrawn units and I will be returning to Inmar, as soon as possible. Upon receipt of this Response Form, Inmar will issue return authorization label(s) Please indicate the # of needed box labels_____.

Sr. No.	Item Description	NDC#	Lot# / Pack Size	Exp. Date	Total Full/Sealed and Partial/Open Pack
1	IMIQUIMOD CREAM USP 5%	68462-536-70	19230117 0.25 g Sachet pack	December - 2024	
2	IMIQUIMOD CREAM USP 5%	68462-536-70	19230225 0.25 g Sachet pack	December - 2024	
3	IMIQUIMOD CREAM USP 5%	68462-536-70	19230447 0.25 g Sachet pack	January - 2025	
4	IMIQUIMOD CREAM USP 5%	68462-536-70	19230562 0.25 g Sachet pack	January - 2025	
5	IMIQUIMOD CREAM USP 5%	68462-536-70	19230688 0.25 g Sachet pack	January - 2025	
6	IMIQUIMOD CREAM USP 5%	68462-536-70	19230766 0.25 g Sachet pack	January - 2025	
7	IMIQUIMOD CREAM USP 5%	68462-536-70	19231268 0.25 g Sachet pack	February - 2025	
8	IMIQUIMOD CREAM USP 5%	68462-536-70	19231312 0.25 g Sachet pack	March - 2025	
9	IMIQUIMOD CREAM USP 5%	68462-536-70	19231503 0.25 g Sachet pack	March - 2025	
10	IMIQUIMOD CREAM USP 5%	68462-536-70	19231588 0.25 g Sachet pack	March - 2025	
11	IMIQUIMOD CREAM USP 5%	68462-536-70	19232359 0.25 g Sachet pack	May - 2025	
12	IMIQUIMOD CREAM USP 5%	68462-536-70	19232558 0.25 g Sachet pack	May - 2025	
13	IMIQUIMOD CREAM USP 5%	68462-536-70	19233809 0.25 g Sachet pack	August - 2025	
14	IMIQUIMOD CREAM USP 5%	68462-536-70	19233971 0.25 g Sachet pack	September - 2025	
15	IMIQUIMOD CREAM USP 5%	68462-536-70	19234256 0.25 g Sachet pack	September - 2025	
16	IMIQUIMOD CREAM USP 5%	68462-536-70	19234436 0.25 g Sachet pack	October - 2025	
17	IMIQUIMOD CREAM USP 5%	68462-536-70	19234677 0.25 g Sachet pack	October - 2025	
18	IMIQUIMOD CREAM USP 5%	68462-536-70	19234851 0.25 g Sachet pack	November - 2025	
19	IMIQUIMOD CREAM USP 5%	68462-536-70	19235006 0.25 g Sachet pack	November - 2025	
20	IMIQUIMOD CREAM USP 5%	68462-536-70	19240226 0.25 g Sachet pack	December - 2025	

If you have any questions regarding this form or product return please contact Inmar at 877-560-5377 Office hours 9am to 5pm EST Mon thru Fri.

Please fax this form to: 817-868-5362 or E-mail rxrecalls@inmar.com

Market Withdrawal Event ID N131255 / RCL320-2024