glenmark
A new way for a new world

URGENT: DRUG RECALL

Chlorpromazine Hydrochloride Tablets, USP 10 mg & 25 mg

(100's Bottles pack Container)

NDC: 68462-861-01 (10 mg) & 68462-862-01 (25 mg)

December 11, 2024

Dear Pharmacy, Wholesale and Retail Customer:

This is to inform you of that Glenmark is initiating a voluntary recall to the Retail level involving the following prescription product:

Chlorpromazine Hydrochloride Tablets, USP 10 mg & 25 mg (100's Pack Container)

S. No.	NDC	Batch #	Pack Size	Expiry
1.	68462-861-01	17230132	100's	12/2024
2.	68462-861-01	17230449	100's	01/2025
3.	68462-862-01	17230133	100's	12/2024

The recall to the **retail level** of the above mentioned product batches for Chlorpromazine Hydrochloride Tablets has been initiated by Glenmark out of an abundance of caution because the results of these finished product is above the Agency's current recommended limit of a nitrosamine, "N-Nitroso-Desmethyl Chlorpromazine impurity" i.e. NMT 0.06625 ppm.

Nitrosamines are common in water and foods, including cured and grilled meats, dairy products, and vegetables. These impurities may increase the risk of cancer if people are exposed to them above acceptable levels over long periods of time, but there is no immediate risk to patients taking this medication and the probability of serious adverse health consequences is remote.

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

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

Glenmark Pharmaceuticals Inc., USA began shipping this product on February 09, 2023 and last shipping date was November 10, 2023.

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.

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 Product recall. Your notification to your retail customers may be enhanced by including a copy of this recall notification letter. Again, this recall should be carried out to the retail level only. Because this is not a consumer level recall, notice to the consumer level is not required.

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 Recall 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 recall return please contact Inmar at 888-792-2392

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

For adverse reactions or quality problems experienced with the use of this product, contact Glenmark's customer service at Global.CustomerService@glenmarkpharma.com or to the FDA's Med Watch Adverse Event Reporting program either online, by regular mail or by fax.

Complete and submit the report Online: www.fda.gov/medwatch/report.htm

Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800- 332-1088 to request a reporting form, then complete and return to the address on the pre- addressed form, or submit by fax to 1-800-FDA-0178.

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

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

Thank you for your cooperation.

Sincerely,

GLENMARK PHARMACEUTICALS INC., USA

Thomas Callaghan

Digitally signed by Thomas Callaghan
Date: 2024.12.11 08:34:39 -05'00'

Thomas Callaghan

Executive Director - Regulatory Affairs, North America

US Agent for Glenmark Pharmaceuticals Limited

Enclosure(s):

Product Labels

Recall Return Response Form

Glenmark Pharmaceuticals Inc. USA 750 Corporate Drive, Mahwah, NJ 07430
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Glenmark
A new way for a new world

Glenmark Pharmaceuticals Inc.

RECALL RETURN RESPONSE FORM

Chlorpromazine Hydrochloride Tablets, USP 10 mg & 25 mg
(100's Bottles pack Container)
NDC: 68462-861-01 (10 mg) & 68462-862-01 (25 mg)
Retail Level
12/11/2024

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 recalled items. **OR**

☐ I have quarantined and listed in the box below the quantity of recalled 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_____.

Item Description	NDC#	Lot#/ Pack Size	Exp. Date	Total Full/Sealed and Partial/Open Bottle Count
Chlorpromazine Hydrochloride Tablets, USP 10 mg	68462-861-01	17230132/100 Tablets	12/2024	

Item Description	NDC#	Lot#/ Pack Size	Exp. Date	Total Full/Sealed and Partial/Open Bottle Count
Chlorpromazine Hydrochloride Tablets, USP 10 mg	68462-861-01	17230449/100 Tablets	01/2025	
Chlorpromazine Hydrochloride Tablets, USP 25 mg	68462-862-01	17230133/100 Tablets	12/2024	

If you have any questions regarding this form or product return please contact Inmar at 888-792-2392 Office hours 9am to 5pm EST Mon thru Fri.

Please fax this form to: 1-817-868-5362 or E-mail rxrecalls@inmar.com
Recall Event ID RCL292-24 / N131241

40 CC
SAME SIZE ARTWORK
LABEL SIZE: 105 mm x 30 mm

Minimum Font Size: 4 pt

DATE: 14-01-2021
VERSION: 08

GLENMARK PHARMACEUTICALS LTD.	**DATE:**	**PANTONE SHADE NO:** Black 186 C NON PRINTING COLOUR	
PRODUCT NAME: Chlorpromazine HCL Tabs 10MG	**PKG. DEV.:**	Item code, Version, Consistency of Design, overprint area, Pack size, Dimensions & Layout	
ITEM CODE: PE57999 **VERSION:** 0121-1	**RA**	Regulatory Text	
PHARMACODE: NA	**PRODUCTION:**	Machine Suitability	
COUNTRY: USA	**QA:**	Entire Text	
LOCATION: INDORE	**REMARKS:**		
PACK : LAB 100'S			
ACTUAL SIZE: 105 mm x 30 mm			
SPECIFICATION:			

FCPDC001/01.00

May Breedlove
Digitally signed by May Breedlove
Date: 2021.01.19 16:25:03 -05'00'

Carole Capella
Digitally signed by Carole Capella
Date: 2021.01.20 09:30:33 -05'00'

Kristin DiStefano
Digitally signed by Kristin DiStefano
Date: 2021.01.20 10:05:09 -05'00'

60 CC
SAME SIZE ARTWORK
LABEL SIZE: 105 mm x 45 mm

Minimum Font Size: 4.8 pt

DATE: 14-01-2021
VERSION: 08

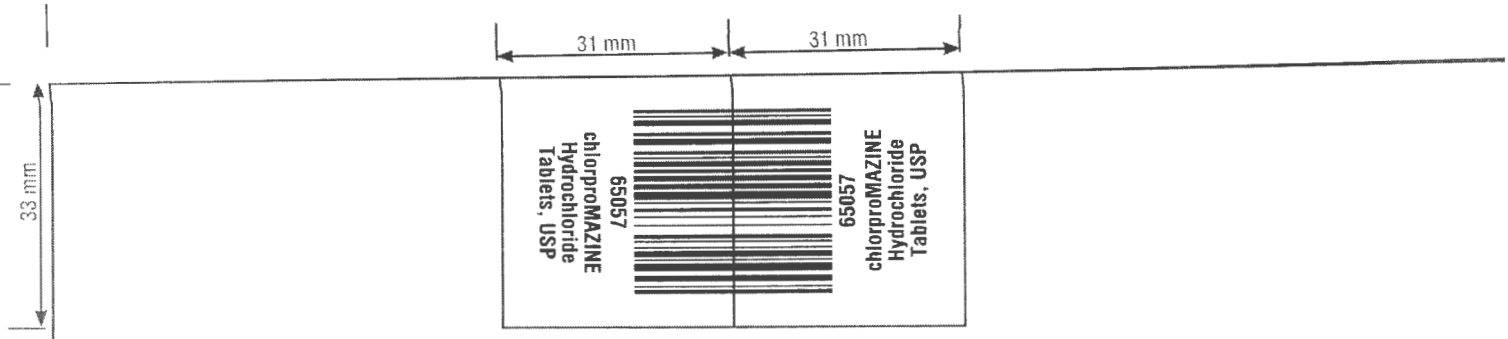
GLENMARK PHARMACEUTICALS LTD.		**DATE:**	**PANTONE SHADE NO:**	Black 186 C 2945 C	NON PRINTING COLOUR
PRODUCT NAME: Chlorpromazine HCL Tabs 25MG		**PKG. DEV.:**	Item code, Version, Consistency of Design, overprint area, Pack size, Dimensions & Layout		
ITEM CODE: PE58000 **VERSION:** 0121-1		**RA**	Regulatory Text		
PHARMACODE: NA		**PRODUCTION:**	Machine Suitability		
COUNTRY: USA		**QA:**	Entire Text		
LOCATION: INDORE		**REMARKS:**			
PACK : LAB 100'S					
ACTUAL SIZE: 105 mm x 45 mm					
SPECIFICATION:					

FCPDC001/01.00

May Breedlove — Digitally signed by May Breedlove Date: 2021.01.19 16:31:32 -05'00'

Carole Capella — Digitally signed by Carole Capella Date: 2021.01.20 09:30:56 -05'00'

Kristin DiStefano — Digitally signed by Kristin DiStefano Date: 2021.01.20 10:07:20 -05'00'



chlorproMAZINE Hydrochloride Tablets, USP

Rx only

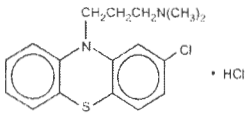
WARNING

Increased Mortality in Elderly Patients with Dementia-Related Psychosis

Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Analyses of seventeen placebo-controlled trials (modal duration of 10 weeks), largely in patients taking atypical antipsychotic drugs, revealed a risk of death in drug-treated patients of between 1.6 to 1.7 times the risk of death in placebo-treated patients. Over the course of a typical 10-week controlled trial, the rate of death in drug-treated patients was about 4.5%, compared to a rate of about 2.6% in the placebo group. Although the causes of death were varied, most of the deaths appeared to be either cardiovascular (e.g., heart failure, sudden death) or infectious (e.g., pneumonia) in nature. Observational studies suggest that, similar to atypical antipsychotic drugs, treatment with conventional antipsychotic drugs may increase mortality. The extent to which the findings of increased mortality in observational studies may be attributed to the antipsychotic drug as opposed to some characteristic(s) of the patients is not clear. Chlorpromazine hydrochloride is not approved for the treatment of patients with dementia-related psychosis (see **WARNINGS**).

DESCRIPTION

Chlorpromazine hydrochloride, a dimethylamine derivative of phenothiazine, has a chemical formula of 2-chloro-10-[3-(dimethylamino) propyl] phenothiazine monohydrochloride. It is available in tablets for oral administration. It has the following structural formula:



Chemical Name: $C_{17}H_{19}ClN_2S.HCl$

Molecular Weight: 355.33 g/mol

Chlorpromazine hydrochloride, USP occurs as white or slightly creamy white crystalline powder.

Each tablet for oral administration contains 10 mg, 25 mg, 50 mg, 100 mg, or 200 mg of chlorpromazine hydrochloride, USP.

Inactive Ingredients:

10 mg contains: corn starch, colloidal silicon dioxide, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone, and sodium starch glycolate. The coating material opadry brown contains diethyl phthalate, D&C yellow no 10, ethylcellulose, FD&C blue no 2, FD&C yellow no 6, hypromellose, red iron oxide, talc, and titanium dioxide.

25 mg contains: corn starch, colloidal silicon dioxide, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone, and sodium starch glycolate. The coating material opadry orange contains diethyl phthalate, D&C yellow no 10, ethylcellulose, FD&C yellow no 6, hypromellose, red iron oxide, talc, and titanium dioxide.

50 mg, 100 mg and 200 mg contains: corn starch, colloidal silicon dioxide, lactose monohydrate, anhydrous lactose, microcrystalline cellulose, magnesium stearate, poloxamer 188 micro, pregelatinized starch, povidone, and sodium starch glycolate. The coating material opadry brown contains diethyl phthalate, D&C yellow no 10, ethylcellulose, FD&C blue no 2, FD&C yellow no 6, hypromellose, red iron oxide, talc, and titanium dioxide.

CLINICAL PHARMACOLOGY

The precise mechanism whereby the therapeutic effects of chlorpromazine are produced is not known. The principal pharmacological actions are psychotropic. It also exerts sedative and antiemetic activity. Chlorpromazine has actions at all levels of the central nervous system – primarily at subcortical levels – as well as on multiple organ systems. Chlorpromazine has strong antiadrenergic and weaker peripheral anticholinergic activity; ganglionic blocking action is relatively slight. It also possesses slight antihistaminic and antiserotonin activity.

INDICATIONS AND USAGE

For the management of manifestations of psychotic disorders.

For the treatment of schizophrenia.

To control nausea and vomiting.

For relief of restlessness and apprehension before surgery.

For acute intermittent porphyria.

As an adjunct in the treatment of tetanus.

To control the manifestations of the manic type of manic-depressive illness.

For relief of intractable hiccups.

For the treatment of severe behavioral problems in children (1 to 12 years of age) marked by combativeness and/or explosive hyperexcitable behavior (out of proportion to immediate provocations), and in the short-term treatment of hyperactive children who show excessive motor activity with accompanying conduct disorders consisting of some or all of the following symptoms: impulsivity, difficulty sustaining attention, aggressivity, mood lability and poor frustration tolerance.

CONTRAINDICATIONS

Do not use in patients with known hypersensitivity to phenothiazines.

Do not use in comatose states or in the presence of large amounts of central nervous system depressants (alcohol, barbiturates, narcotics, etc.).

WARNINGS

Increased Mortality in Elderly Patients with Dementia-Related Psychosis

Elderly patients with dementia-related psychosis treated with antipsychotic drugs are

and symptoms of the syndrome and therapy may possibly mask the underlying disease process. The effect that symptomatic suppression has upon the long-term course of the syndrome is unknown.

Given these considerations, antipsychotics should be prescribed in a manner that is most likely to minimize the occurrence of tardive dyskinesia. Chronic antipsychotic treatment should generally be reserved for patients who suffer from a chronic illness that, 1) is known to respond to antipsychotic drugs, and, 2) for whom alternative, equally effective, but potentially less harmful treatments are **not** available or appropriate. In patients who do require chronic treatment, the smallest dose and the shortest duration of treatment producing a satisfactory clinical response should be sought. The need for continued treatment should be reassessed periodically.

If signs and symptoms of tardive dyskinesia appear in a patient on antipsychotics, drug discontinuation should be considered. However, some patients may require treatment despite the presence of the syndrome.

For further information about the description of tardive dyskinesia and its clinical detection, please refer to the sections on **PRECAUTIONS** and **ADVERSE REACTIONS**.

Neuroleptic Malignant Syndrome (NMS): A potentially fatal symptom complex sometimes referred to as Neuroleptic Malignant Syndrome (NMS) has been reported in association with antipsychotic drugs. Clinical manifestations of NMS are hyperpyrexia, muscle rigidity, altered mental status and evidence of autonomic instability (irregular pulse or blood pressure, tachycardia, diaphoresis, and cardiac dysrhythmias).

The diagnostic evaluation of patients with this syndrome is complicated. In arriving at a diagnosis, it is important to identify cases where the clinical presentation includes both serious medical illness (e.g., pneumonia, systemic infection, etc.) and untreated or inadequately treated extrapyramidal signs and symptoms (EPS). Other important considerations in the differential diagnosis include central anticholinergic toxicity, heat stroke, drug fever and primary central nervous system (CNS) pathology.

The management of NMS should include 1) immediate discontinuation of antipsychotic drugs and other drugs not essential to concurrent therapy, 2) intensive symptomatic treatment and medical monitoring, and 3) treatment of any concomitant serious medical problems for which specific treatments are available. There is no general agreement about specific pharmacological treatment regimens for uncomplicated NMS.

If a patient requires antipsychotic drug treatment after recovery from NMS, the potential reintroduction of drug therapy should be carefully considered. The patient should be carefully monitored, since recurrences of NMS have been reported.

An encephalopathic syndrome (characterized by weakness, lethargy, fever, tremulousness and confusion, extrapyramidal symptoms, leukocytosis, elevated serum enzymes, BUN and FBS) has occurred in a few patients treated with lithium plus an antipsychotic. In some instances, the syndrome was followed by irreversible brain damage. Because of a possible causal relationship between these events and the concomitant administration of lithium and antipsychotics, patients receiving such combined therapy should be monitored closely for early evidence of neurologic toxicity and treatment discontinued promptly if such signs appear. This encephalopathic syndrome may be similar to or the same as neuroleptic malignant syndrome (NMS).

Patients with bone marrow depression or who have previously demonstrated a hypersensitivity reaction (e.g., blood dyscrasias, jaundice) with a phenothiazine, should not receive any phenothiazine, including chlorpromazine, unless in the judgment of the physician the potential benefits of treatment outweigh the possible hazard.

Chlorpromazine may impair mental and/or physical abilities, especially during the first few days of therapy. Therefore, caution patients about activities requiring alertness (e.g., operating vehicles or machinery).

The use of alcohol with this drug should be avoided due to possible additive effects and hypotension.

Chlorpromazine may counteract the antihypertensive effect of guanethidine and related compounds.

Falls

Chlorpromazine may cause somnolence, postural hypotension, motor and sensory instability, which may lead to falls and, consequently, fractures or other injuries. For patients with diseases, conditions, or medications that could exacerbate these effects, complete fall risk assessments when initiating antipsychotic treatment and recurrently for patients on long-term antipsychotic therapy.

Usage in Pregnancy: Safety for the use of chlorpromazine during pregnancy has not been established. Therefore, it is not recommended that the drug be given to pregnant patients except when, in the judgment of the physician, it is essential. The potential benefits should clearly outweigh possible hazards. There are reported instances of prolonged jaundice, extrapyramidal signs, hyperreflexia or hyporeflexia in newborn infants whose mothers received phenothiazines.

Reproductive studies in rodents have demonstrated potential for embryotoxicity, increased neonatal mortality and nursing transfer of the drug. Tests in the offspring of the drug–treated rodents demonstrate decreased performance. The possibility of permanent neurological damage cannot be excluded.

Non-teratogenic Effects: Neonates exposed to antipsychotic drugs, during the third trimester of pregnancy are at risk for extrapyramidal and/or withdrawal symptoms following delivery. There have been reports of agitation, hypertonia, hypotonia, tremor, somnolence, respiratory distress and feeding disorder in these neonates. These complications have varied in severity; while in some cases symptoms have been self-limited, in other cases neonates have required intensive care unit support and prolonged hospitalization.

Chlorpromazine Hydrochloride should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers: There is evidence that chlorpromazine is excreted in the breast milk of nursing mothers. Because of the potential for serious adverse reactions in nursing infants from chlorpromazine, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

PRECAUTIONS

due to cirrhosis have increased sensi
impaired cerebration and abnormal slo

Because of its CNS depressant effect,
patients with chronic respiratory disord
respiratory infections, particularly in ch

Because chlorpromazine can suppress

Chlorpromazine prolongs and intens
anesthetics, barbiturates and narco
concomitantly, about ¼ to ½ the us
chlorpromazine is not being administer
is best to stop such depressants before
may subsequently be reinstated at low

Note: Chlorpromazine does **not** inter
Therefore, dosage of anticonvulsants,
chlorpromazine is started. Instead, sta
needed.

Use with caution in persons who will
insecticides, and in persons receiving at

Antipsychotic drugs elevate prolactin
administration. Tissue culture experim
breast cancers are prolactin-dependen
the prescribing of these drugs is conte
breast cancer. Although disturbances s
and impotence have been reported, the
levels is unknown for most patients.
found in rodents after chronic administr
epidemiologic studies conducted to date
chronic administration of these drugs
evidence is considered too limited to be

Chromosomal aberrations in spermatocyt
in rodents treated with certain neuroleptic

As with all drugs which exert an ar
chlorpromazine should be used with caut

Chlorpromazine diminishes the effect of

Phenothiazines can produce alpha-adre
the convulsive threshold; dosage adjust
Potentiation of anticonvulsant effects do
that chlorpromazine may interfere with th
phenytoin toxicity.

Concomitant administration with propran
drugs.

Thiazide diuretics may accentuate the
phenothiazines.

The presence of phenothiazines may proc
results.

Drugs which lower the seizure threshold
not be used with metrizamide. As with ot
should be discontinued at least 48 hours
for at least 24 hours post-procedure, and
and vomiting occurring either prior to mye

Long-Term Therapy: To lessen the likelihc
drug effect, patients with a history of lo
other antipsychotics should be evaluated
dosage could be lowered or drug therapy

Antiemetic Effect: The antiemetic action
symptoms of overdosage of other drugs
of other conditions such as intestinal ob
(See **WARNINGS**).

When chlorpromazine is used with cancer
the toxicity of these agents may be obscur

Abrupt Withdrawal: Like other phenothia
psychic dependence and does not proc
however, following abrupt withdrawal of hi
those of physical dependence such as
tremulousness. These symptoms can usua
of the dosage or by continuing concomita
after chlorpromazine is withdrawn.

ADVERSE REACTIONS

Note: Some adverse effects of chlorprom
with greater intensity, in patients with spec
insufficiency or pheochromocytoma hav
recommended doses.

Drowsiness: Usually mild to moderate, ma
week, after which it generally disappears.

Jaundice: Overall incidence has been lo
investigators conclude it is a sensitivity re
and fourth weeks of therapy. The clinica
laboratory features of obstructive jaundice
is usually promptly reversible on withdraw
has been reported.

There is no conclusive evidence that pr
susceptible to jaundice. Alcoholics with
chlorpromazine without complications.
cautiously in patients with liver disease.
a phenothiazine should not, if possible

To control hypotension, place patient in head–low position with legs raised. If a vasoconstrictor is required, norepinephrine and phenylephrine are the most suitable. Other pressor agents, including epinephrine, should not be used as they may cause a paradoxical further lowering of blood pressure.

EKG Changes– particularly nonspecific, usually reversible Q and T wave distortions - have been observed in some patients receiving phenothiazine tranquilizers, including chlorpromazine.

Note: Sudden death, apparently due to cardiac arrest, has been reported.

CNS Reactions:

Extrapyramidal Symptoms– Neuromuscular reactions include dystonias, motor restlessness, pseudo-parkinsonism and tardive dyskinesia, and appear to be dose-related. They are discussed in the following paragraphs:

Dystonia:

Class effect: Symptoms of dystonia, prolonged abnormal contractions of muscle groups, may occur in susceptible individuals during the first few days of treatment. Dystonic symptoms include: spasm of the neck muscles, sometimes progressing to tightness of the throat, swallowing difficulty, difficulty breathing, and/or protrusion of the tongue. While these symptoms can occur at low doses, they occur more frequently and with greater severity with high potency and at higher doses of first generation antipsychotic drugs. An elevated risk of acute dystonia is observed in males and younger age groups.

Motor Restlessness: Symptoms may include agitation or jitteriness and sometimes insomnia. These symptoms often disappear spontaneously. At times these symptoms may be similar to the original neurotic or psychotic symptoms. Dosage should not be increased until these side effects have subsided.

If these symptoms become too troublesome, they can usually be controlled by a reduction of dosage or change of drug. Treatment with anti–parkinsonian agents, benzodiazepines or propranolol may be helpful.

Pseudo – parkinsonism: Symptoms may include: mask-like facies, drooling, tremors, pillrolling motion, cogwheel rigidity and shuffling gait. In most cases these symptoms are readily controlled when an anti–parkinsonism agent is administered concomitantly. Anti–parkinsonism agents should be used only when required. Generally, therapy of a few weeks to 2 or 3 months will suffice. After this time patients should be evaluated to determine their need for continued treatment. (**Note:** Levodopa has not been found effective in antipsychotic–induced pseudo–parkinsonism.) Occasionally, it is necessary to lower the dosage of chlorpromazine or to discontinue the drug.

Tardive Dyskinesia: As with all antipsychotic agents, tardive dyskinesia may appear in some patients on long-term therapy or may appear after drug therapy has been discontinued. The syndrome can also develop, although much less frequently, after relatively brief treatment periods at low doses. This syndrome appears in all age groups. Although its prevalence appears to be highest among elderly patients, especially elderly women, it is impossible to rely upon prevalence estimates to predict at the inception of antipsychotic treatment which patients are likely to develop the syndrome. The symptoms are persistent and in some patients appear to be irreversible. The syndrome is characterized by rhythmical involuntary movements of the tongue, face, mouth or jaw (e.g., protrusion of tongue, puffing of cheeks, puckering of mouth, chewing movements). Sometimes these may be accompanied by involuntary movements of extremities. In rare instances, these involuntary movements of the extremities are the only manifestations of tardive dyskinesia. A variant of tardive dyskinesia, tardive dystonia, has also been described.

There is no known effective treatment for tardive dyskinesia; anti-parkinsonism agents do not alleviate the symptoms of this syndrome. If clinically feasible, it is suggested that all antipsychotic agents be discontinued if these symptoms appear. Should it be necessary to reinstitute treatment, or increase the dosage of the agent, or switch to a different antipsychotic agent, the syndrome may be masked.

It has been reported that fine vermicular movements of the tongue may be an early sign of the syndrome and, if the medication is stopped at that time, the syndrome may not develop.

Adverse Behavioral Effects– Psychotic symptoms and catatonic-like states have been reported rarely.

Other CNS Effects– Neuroleptic Malignant Syndrome (NMS) has been reported in association with antipsychotic drugs. (See **WARNINGS**).

Cerebral edema has been reported.

Convulsive seizures (petit mal and grand mal) have been reported, particularly in patients with EEG abnormalities or history of such disorders.

Abnormality of the cerebrospinal fluid proteins has also been reported.

Allergic Reactions of a mild urticarial type of photosensitivity are seen. Avoid undue exposure to sun. More severe reactions, including exfoliative dermatitis and toxic epidermal necrolysis (TEN), have been reported occasionally.

Contact dermatitis has been reported in nursing personnel; accordingly, the use of rubber gloves when administering chlorpromazine liquid or injectable is recommended.

In addition, asthma, laryngeal edema, angioneurotic edema and anaphylactoid reactions have been reported.

Endocrine Disorders: Lactation and moderate breast engorgement may occur in females on large doses. If persistent, lower dosage or withdraw drug. False-positive pregnancy tests have been reported, but are less likely to occur when a serum test is used. Amenorrhea and gynecomastia have also been reported. Hyperglycemia, hypoglycemia and glycosuria have been reported.

Autonomic Reactions: Occasional dry mouth; nasal congestion; nausea; obstipation; constipation; adynamic ileus; urinary retention, priapism; miosis and mydriasis, atonic colon, ejaculatory disorders/impotence.

Special Considerations In Long-Term Therapy: Skin pigmentation and ocular changes have occurred in some patients taking substantial doses of chlorpromazine for prolonged periods.

Skin Pigmentation– Rare instances of skin pigmentation have been observed in hospitalized mental patients, primarily females who have received the drug usually for 3 against the possible risks and, on the merits of the individual case, determine whether or not to continue present therapy, lower the dosage, or withdraw the drug.

Other Adverse Reactions: Mild fever may occur after large I.M. doses. Hyperpyrexia has been reported. Increases in appetite and weight sometimes occur. Peripheral edema and a systemic lupus erythematosus-like syndrome have been reported.

Note: There have been occasional reports of sudden death in patients receiving phenothiazines. In some cases, the cause appeared to be cardiac arrest or asphyxia due to failure of the cough reflex.

To report SUSPECTED ADVERSE REACTIONS, contact Glenmark Pharmaceuticals Inc., USA at 1 (888) 721-7115 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

OVERDOSAGE

(See also **ADVERSE REACTIONS**.)

Symptoms

Primarily symptoms of central nervous system depression to the point of somnolence or coma.

Hypotension and extrapyramidal symptoms.

Other possible manifestations include agitation and restlessness, convulsions, fever, autonomic reactions such as dry mouth and ileus. EKG changes and cardiac arrhythmias.

Treatment

It is important to determine other medications taken by the patient since multiple drug therapy is common in overdosage situations. Treatment is essentially symptomatic and supportive. Early gastric lavage is helpful. Keep patient under observation and maintain an open airway, since involvement of the extrapyramidal mechanism may produce dysphagia and respiratory difficulty in severe overdosage. **Do not attempt to induce emesis because a dystonic reaction of the head or neck may develop that could result in aspiration of vomitus.** Extrapyramidal symptoms may be treated with anti-parkinsonism drugs, barbiturates, or diphenhydramine hydrochloride. See prescribing information for these products. Care should be taken to avoid increasing respiratory depression.

If administration of a stimulant is desirable, amphetamine, dextroamphetamine, or caffeine with sodium benzoate is recommended. Stimulants that may cause convulsions (e.g., picrotoxin or pentylenetetrazol) should be avoided.

If hypotension occurs, the standard measures for managing circulatory shock should be initiated. If it is desirable to administer a vasoconstrictor, norepinephrine and phenylephrine are most suitable. Other pressor agents, including epinephrine, are not recommended because phenothiazine derivatives may reverse the usual elevating action of these agents and cause a further lowering of blood pressure.

Limited experience indicates that phenothiazines are **not** dialyzable.

DOSAGE AND ADMINISTRATION–ADULTS

Adjust dosage to individual and the severity of his condition, recognizing that the milligram for milligram potency relationship among all dosage forms has not been precisely established clinically. It is important to increase dosage until symptoms are controlled. Dosage should be increased more gradually in debilitated or emaciated patients. In continued therapy, gradually reduce dosage to the lowest effective maintenance level, after symptoms have been controlled for a reasonable period.

The 100 mg and 200 mg tablets are for use in severe neuropsychiatric conditions.

Elderly Patients – In general, dosages in the lower range are sufficient for most elderly patients. Since they appear to be more susceptible to hypotension and neuromuscular reactions, such patients should be observed closely. Dosage should be tailored to the individual, response carefully monitored, and dosage adjusted accordingly. Dosage should be increased more gradually in elderly patients.

Psychotic Disorders – Increase dosage gradually until symptoms are controlled. Maximum improvement may not be seen for weeks or even months. Continue optimum dosage for 2 weeks; then gradually reduce dosage to the lowest effective maintenance level. Daily dosage of 200 mg is not unusual. Some patients require higher dosages (e.g., 800 mg daily is not uncommon in discharged mental patients).

Hospitalized Patients:

Acute Schizophrenic or Manic States – It is recommended that initial treatment be with chlorpromazine hydrochloride injection until patient is controlled. Usually patient becomes quiet and co-operative within 24 to 48 hours and oral doses may be substituted and increased until the patient is calm. 500 mg a day is generally sufficient. While gradual increases to 2,000 mg a day or more may be necessary, there is usually little therapeutic gain to be achieved by exceeding 1,000 mg a day for extended periods. In general, dosage levels should be lower in the elderly, the emaciated and the debilitated.

Less Acutely Disturbed – 25 mg t.i.d. Increase gradually until effective dose is reached – usually 400 mg daily.

Outpatients – 10 mg t.i.d. or q.i.d., or 25 mg b.i.d. or t.i.d.

More Severe Cases – 25 mg t.i.d. After 1 or 2 days, daily dosage may be increased by 20 to 50 mg at semi-weekly intervals until patient becomes calm and cooperative.

Prompt Control of Severe Symptoms – Initial treatment should be with intramuscular chlorpromazine. Subsequent doses should be oral, 25 to 50 mg t.i.d.

Nausea and Vomiting– 10 to 25 mg q4 to 6h, p.r.n., increased, if necessary.

Presurgical Apprehension– 25 to 50 mg, 2 to 3 hours before the operation.

Intractable Hiccups– 25 to 50 mg t.i.d. or q.i.d. If symptoms persist for 2 to 3 days, parenteral therapy is indicated.

Acute Intermittent Porphyria– 25 to 50 mg t.i.d. or q.i.d. Can usually be discontinued after several weeks, but maintenance therapy may be necessary for some patients.

DOSAGE AND ADMINISTRATION – PEDIATRIC PATIENTS (6 months to 12 years of age)

Chlorpromazine should generally not be used in pediatric patients under 6 months of age except where potentially lifesaving. It should not be used in conditions for which specific pediatric dosages have not been established.

Severe Behavioral Problems

They are available as follows:
Bottles of 100's with child-resistant closu
Bottles of 1000's, NDC 68462-861-10
Chlorpromazine Hydrochloride Tablets, round, biconvex film-coated tablets, debo side.
They are available as follows:
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Bottles of 1000's, NDC 68462-862-10
Chlorpromazine Hydrochloride Tablets, U colored, round, biconvex film-coated tab the other side.
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Bottles of 1000's, NDC 68462-863-10
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Chlorpromazine Hydrochloride Tablets, U colored, round, biconvex film-coated tab on the other side.
They are available as follows:
Bottles of 100's with child-resistant closu
Bottles of 1000's, NDC 68462-865-10
Store at 20°C to 25°C (68°F to 77°F); excu [see USP Controlled Room Temperature.]
This package is not for household dispe closed, light-resistant, child-resistant cont
Keep out of reach of children.

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