HOW SUPPLIED: Thiothixene Capsules, USP are available containing 1 mg, 2 mg, 5 mg, or 10 mg of thiothixene, USP.

The 2 mg capsule is a hard-shell gelatin capsule with a caramel opaque cap and a white opaque body filled with white to off-white powder. The capsule is acid-insoluble with MYLAR over 2002 in black ink on both the cap and body. They are available as follows: NDC 51075-589-20 - Unit dose blister packages of 100 (10 cards of 10 capsules each).

The 5 mg capsule is a hard-shell gelatin capsule with a caramel opaque cap and a white opaque body filled with white to off-white powder. The capsule is acid-insoluble with MYLAR over 2002 in black ink on both the cap and body. They are available as follows: NDC 51075-588-20 - Unit dose blister packages of 100 (10 cards of 10 capsules each).

The 10 mg capsule is a hard-shell gelatin capsule with a caramel opaque cap and a peach opaque body filled with white to off-white powder. The capsule is acid-insoluble with MYLAR over 2002 in black ink on both the cap and body. They are available as follows: NDC 51075-589-20 - Unit dose blister packages of 100 (10 cards of 10 capsules each).

Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature].

Protect from light.

REFERENCES
1. Worldwide Labeling Safety Report: Dyskinesia and Dyskinesia Ter-
3. Worldwide Labeling Safety Report: Hyperprolactinemia and Thio-
4. Erdoslevyi L, Saldan SR, Watanabe MD, et al. Thiothixene Pharma-
5. Worldwide Labeling Safety Report: Drug Interaction and Thio-
7. Worldwide Labeling Safety Report: Menstrual Disorder and Thio-

DESCRIPTION: Thiothixene is a thioxanthene derivative. Specifically, it is the cis isomer of 1-N,N-dimethyl-3-(4-methyl-1-piperazinyl)propyl-
dimethylthiothixene-2-sulfonamide. It may be represented by the follow-
ing structural formula:
cardiac dysrhythmias).

The clinical diagnosis of patients with this syndrome is compli-
cated. In arriving at a diagnosis, it is important to identify causes like
those described above (e.g., withdrawal, including tardive syndrome,
prolonged abnormal

Drug Interactions:

Pseudoparkinsonism, akathisia and dystonia have been reported (see

Animal reproduction studies and clinical experience to date have not
demonstrated any adverse effect attributable to thiothixene on repro-
duction in rats or rabbits. Similar findings have been reported with
risperidone, another atypical antipsychotic. 

1.2 5 15 mg/day, rabbits (3 30 50 mg/day; and mon-
key 1 2 5 10 mg/kg/day) before and during gestation, no teratogenic
effects were seen. 

Usage in Children: The use of thiothixene in children under 12 years of age is not recommended because safe conditions for its use have not
been established. Therefore, this drug should be given to pregnant
women only when clear benefit justifies the potential risk to the mother. 

Neuroleptic Malignant Syndrome (NMS):

An atypical antipsychotic should be considered in the differential
diagnosis for patients with unexplained hyperpyrexia, hyperthermia,
and altered mental status. These patients should be monitored on an
ongoing basis. It has been reported that fine movements of the
tongue, face, mouth or jaw (e.g., protrusion of tongue, puffing of
cheeks) \[4,5\].

Contraindications:

A persistent, severe, and unbearable dyskinesia may be accompanied by involuntary movements of extremities. 

Since early detection of tardive dyskinesia is important, patients
should be monitored on a continuing basis. It is recommended that the
clinician should consider possible discontinuation of antipsychotic
medication. (See WARNINGS.)

Adverse Reactions:

Drug Interactions:

Neuroendocrine changes: In many cases, the syndrome is not accompanied by involuntary movements of extremities. 

Seizures and paradoxical exacerbation of psychotic symptoms have
occurred infrequently with thiothixene therapy. Phenothiazines have
been associated with a number of serious medical problems, including
boils, pseudoparkinsonism, akathisia and dystonia have been reported
with thiothixene infrequently.

Hyperpyrexia, anorexia, nausea, vomiting, volvulus, and bradycardia have been reported. (See Precautions.) 

Endocrine/Reproductive:

Hyperpyrexia, afebrile, and mental status changes that are indistinguishable from a convulsion or seizure may be associated with agranulocytosis, eosinophilia, hematologic, thymic atrophy and psychomotor retardation. 

Allergic Reactions: Rash, pruritus, urticaria, photosensitivity and rare anaphylactic reactions have been reported. 

Hepatic Effects:

Pseudoparkinsonism, akathisia and dystonia have been reported (see

Extrapyramidal symptoms, such as 

The management of NMS should include 1) immediate discontinua-
ion 2) assessment of concomitant serious medical problems for any
potential exacerbation of the NMS. 

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ion 2) assessment of concomitant serious medical problems for any
potential exacerbation of the NMS. 

In consideration of the known capability of thiothixene and certain
phenothiazines to increase prolactin levels in patients, it is important to
declare that all patients with galactorrhea or gynecomastia or a suspi-
cion of patients treated with thiothixene for pro-
longed periods). Blood dyscrasias (agranulocytosis, pancytopenia, thrombocytopenia and eosinophilia) are usually seen in patients who have
been reported with related drugs.

Antipsychotics, including thiothixene, may mask signs of overdosage of toxic drugs and may

The use of thiothixene capsules in children under 12 years of age is
not recommended because safe conditions for its use have not
been established. 

In more severe conditions, an initial dose of 5 mg twice daily is rec-
ommended. The usual daily dose is 20 mg three times daily and the
usual maintenance dose in adults is 60 mg three times daily (20 mg orally
on nursing personnel) have been reported with certain phenothiazines. 

Nursing Mothers:

The incidence of drug-related extrapyramidal symptoms, such as 

The incidence of drug-related extrapyramidal symptoms, such as 

Elevations of serum transaminase and alkaline phosphatase activity have been reported in patients treated with thiothixene.

Hyperpyrexia or frank fever is not a feature of this syndrome. (See Precautions.) 

Prophylactic Treatment:

As with all antipsychotic agents, tar-
diantidipsia may be accompanied by involuntary movements of extremities. 

The incidence of drug-related extrapyramidal symptoms, such as 

Elevations of serum transaminase and alkaline phosphatase activity have been reported in patients treated with thiothixene.

Endocrine/Reproductive: 

Hyperprolactinemia and prolactin-dependent galactorrhea may be associated with thiothixene therapy in patients who have received certain phenothiazine derivatives. In some cases, the cause of the disease was apparently central or hypothalamic due to failure of the cough reflex. In others, the cause could not be determined. 

NOTE: 

Seizures and paradoxical exacerbation of psychotic symptoms have
occurred infrequently with thiothixene therapy. Phenothiazines have

Also, careful evaluation of the extrapyramidal and retinal toxicity is necessary before starting therapy, since a latent period of several months to years may be involved. 

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been reported with related drugs.
HOW SUPPLIED: Thiothixene Capsules, USP are available containing 1 mg, 2 mg, 5 mg, or 10 mg of thiothixene, USP.

The 2 mg capsule is a hard-shell gelatin capsule with a caramel opaque cap and a white opaque body filled with white to off-white powder. The capsule is axially imprinted with MYLAN over 1032  in black ink on both the cap and body. They are available as follows: NDC 51079-588-94 - Unit dose blister packages of 100 (10 cards of 10 capsules each). The 10 mg capsule is a hard-shell gelatin capsule with a caramel opaque cap and a peach opaque body filled with white to off-white powder. The capsule is axially imprinted with MYLAN over 8198  in black ink on both the cap and body. They are available as follows: NDC 51079-589-94 - Unit dose blister packages of 100 (10 cards of 10 capsules each).

Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature.]

Protect from light.

REFERENCES

1. Worldwide Labeling Safety Report: Dyskinesia and Dyskinesia Tar-
   dive and Thiothixene, (16Apr02).

2. Worldwide Labeling Safety Report: Neuroleptic Malignant Syndrome
   and Thiothixene, (16Apr02).

3. Worldwide Labeling Safety Report: Hyperprolactinemia and Thio-
   thixene, (16Apr02).

4. Eroshevsky L, Saladj SR, Waterman MD, et al. Thiothixene Pharma-
   cotherapy: A Study of Hepatic Enzyme Inductors, Change Inhibitors, and Demographic Variables. Journal of Clinical Psy-

5. Worldwide Labeling Safety Report: Drug Interaction and Thio-
   thixene, (16Apr02).


7. Worldwide Labeling Safety Report: Menstrual Disorder and Thio-
   thixene, (16Apr02).

DESCRIPTION: Thiothixene is a thioxanthene derivative. Specifically, it is the cis isomer of N,N-dimethyl-(3-(4-methyl-1-piperazinyl)propi-

THIOTHIXENE CAPSULES, USP

Manufactured by:
Mylan Pharmaceuticals Inc.
Morgantown, WV 26505 U.S.A.

Distributed by:
Mylan Institutional Inc.
Rockford, IL 61103 U.S.A.

CLINICAL PHARMACOLOGY: Thiothixene is an antipsychotic of the thioxanthene series. Thiothixene possesses certain chemical and phar-

macological similarities to the piperazine phenothiazines and differ-

ces from the aliphatic group of thioxanthenes.

INDICATIONS AND USAGE: Thiothixene capsules are effective in the management of schizophrenia. Thiothixene capsules have not been evaluated in the management of behavioral complications in patients with mental retardation.

CONTRAINDICATIONS: Thiothixene capsules are contraindicated in patients with a history of a drug allergy associated with the thioxanthene series. Thiothixene capsules should not be prescribed to patients who are known to be hypersensitive to the thioxanthenes and the phenotype derivatives, but this possibility should be considered when the product is prescribed.

WARNINGS: Increased Mortality in Elderly Patients with Dementia-Related Psychosis: Elderly patients with dementia-related psychosis treated with antipsychotic drugs, including thio-

thixene is not approved for the treatment of patients with dementia-

related psychosis (see BOXED WARNING).

Tardive Dyskinesia: Tardive dyskinesia, a syndrome consisting of potentially irreversible, involuntary, dyskinetic movements may develop in patients treated with antipsychotic drugs, including thio-

thixene. Although the prevalence of the syndrome appears to be highest among the elderly, especially elderly women, it is impossible to rely upon prevalence estimates to predict, at the inception of antipsychotic treat-

ment, which patients are likely to develop the syndrome. Whether antipsychotic drug products differ in their potential to cause tardive dyskinesia is unknown.

Both the risk of developing the syndrome and the likelihood that it will become irreversible are believed to increase as the duration of treat-

ment and the cumulative dose of antipsychotic drugs administered to the patient increase. However, the syndrome can develop, although much less commonly, after relatively brief treatment periods at low doses.

There is no known treatment for established cases of tardive dysk-

nnesia, although the syndrome may remit, partially or completely, if antipsychotic treatment is withdrawn. Antipsychotic treatment, itself, however, may suppress (or partially suppress) the signs and symptoms of the syndrome and thereby may possibly mask the underlying dis-

ease 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 dysk-

nnesia. Chronic antipsychotic treatment should generally be reserved for patients who suffer from a chronic disease (e.g., schizoaffective disorder) which 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 not 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 antipsychotic drug therapy, drug discontinuation should be considered. However, in some patients some may require treatment despite the presence of the syn-

drome.

(For further information about the description of tardive dyskinesia and its clinical detection, please refer to Information for Patients in the PRECAUTIONS section, and to the ADVERSE REACTIONS section.)

Neurologic Malignant Syndrome (NMS): A potentially fatal symptom complex sometimes referred to as Neurologic Malignant Syndrome (NMS) has been reported in association with antipsychotic drugs, including thiothixene. Clinical manifestations of NMS are hyperpyrexia, muscle rigidity, altered mental status and evidence of autonomic insta-

bility (irregular pulse or blood pressure, tachycardia, diaphoresis, and