

**WHAT IS IN THIS LEAFLET?**

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**Read this entire leaflet before you start taking the medication.**

- Keep this leaflet. You may need to read again.
- Ask your doctor or pharmacist if you need more information or advice.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

**1. WHAT TUMAX IS USED FOR**

Tumax is used to treat ulcers and irritable bowel syndrome. It helps relieve stomach spasms and abdominal cramps.

**2. HOW TUMAX WORKS**

Tumax contains the active ingredient Chlordiazepoxide hydrochloride and Clidinium bromide.

Chlordiazepoxide belongs to a group of medicine called benzodiazepines. It affects the chemicals in the brain that may become unbalanced which resulting in anxiety. Anxiety is one of the main causes of excessive stomach acid production.

Clidinium bromide is antimuscarinic agent. It reduces stomach acid and decreases intestinal spasm.

**3. BEFORE YOU TAKE TUMAX****Do not take Tumax if you:**

- Have ever had a reaction or been told that

you are allergic to chlordiazepoxide and clidinium bromide.

- Have glaucoma.
- Have blocked urine flow.
- Have *myasthenia gravis* (problems with nerves and muscles causing muscles weakness).
- Have rapid heartbeat due to heart failure or *thyrotoxicosis* (excess thyroid hormone).
- Have bleeding problem particularly with unstable heart status.

**Before you start to take it**

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you:

- Have *hyperthyroidism* (thyroid gland makes too much thyroid hormone).
- Have any liver or kidney problems.
- Have any heart problems.
- Have diarrhea.
- Have ulcerative colitis (inflammation of the intestine).

*If you are not sure whether you should start taking this medicine, consult your doctor.*

**Taking / using other medicines**

Inform your doctor or pharmacist if you are taking or if you have recently taken any other medicines, including medicines obtained without a prescription.

Some medicines and Tumax may interfere with each other. It is important to tell your doctor or pharmacist if you are taking:

- Antacids or diarrhea medication containing kaolin or attapulgate.
- Central nervous system (CNS) depressant e.g. *barbiturates* (phenobarbital) and *benzodiazepines* (diazepam).
- Anticholinergic drugs e.g. *dicycloverine*
- Antifungal e.g. *ketoconazole*
- *Potassium chloride*, to prevent or to treat low potassium levels in blood.

**Pregnancy and breast-feeding**

Ask your doctor or pharmacist for advice before taking any medicine.

Use of medicine containing Chlordiazepoxide during pregnancy may cause harm to your baby. Tumax is not recommended to be used during pregnancy. Inform your doctor immediately if you become pregnant during treatment.

Chlordiazepoxide and clidinium may pass into breast milk. Do not use this medicine if you are breastfeeding.

**4. HOW TO TAKE TUMAX**

Always take Tumax exactly according to the instructions given to you by your doctor or pharmacist. Check with your doctor or pharmacist if you are not sure.

Dosage given by your doctor may differ from this leaflet.

**How much to take:**

The usual dosage is 1 capsule 3 or 4 times a day, 30 to 60 minutes before meals and at bedtime and not more than 8 capsules daily.

**Geriatric patients**

The initial dosage is not more than 1 capsules 2 times a day. Your doctor will adjust the dosage depending on your response.

**When to take it**

Take your medicine at the same time every day. Tumax should be taken 30 to 60 minutes before meal and at bed time.

**How long to take it**

Do not take Tumax for longer period than your doctor directed. Continuous long term use is not recommended unless advised by your doctor.

*Prolonged continuous use of benzodiazepines may lead to dependence on the medicine.*

**If you forget to take it**

Take your dose as soon as you remember and continue to take it as you would normally. If it is time for your next dose,

## Tumax Capsule

Chlordiazepoxide hydrochloride & Clidinium bromide

Patient Information Leaflet

skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

### If you take too much (overdose)

If you or anyone else takes too many tablets, you should immediately go to your nearest hospital emergency department or tell your doctor. Do this even if there are no signs of discomfort or poisoning. Take the carton or any remaining tablets you have with you.

The following symptoms may be observed in overdose:

- Somnolence (drowsiness)
- Impaired coordination
- Slurred speech
- Confusion
- Blurred vision
- Diminished reflexes

*If you have any further questions on the use of this product, ask your doctor or pharmacist.*

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## 5. WHILE YOU ARE USING TUMAX

### Things you must do

- Always take Tumax exactly according to the instructions given to you by your doctor or pharmacists. If you are unsure, check with your doctor or pharmacist.
- Inform your doctor or pharmacist if you are taking or if you have recently taken any other medicines, including medicines obtained without a prescription such as supplements or traditional medicines.
- Tell your doctor or pharmacist immediately if you notice any side effects, or if the side effects gets serious or anything else that make you feel unwell.
- If you become pregnant, or plan on becoming pregnant while taking Tumax tells your doctor immediately.
- If you are about to be started on a new medicine, remind your doctor and pharmacist that you are taking Tumax.

### Things you must not do

- Do not stop taking or change the dose of your medicines without consulting your doctor.
- Do not use Tumax after the expiry date which is stated on the carton and blister.
- Do not give this medication to anyone else, even if they have the same condition as you.

### Things to be careful of

- Taking Tumax may cause dizziness or light-headedness. If you have any of these symptoms, do not drive or operate any machinery.
- Taking Tumax with alcohol and other CNS depressants can worsen the effects of dizziness or light-headedness.

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## 6. POSSIBLE SIDE EFFECTS

Like many medicines, Tumax may cause side effects in some patients, particularly when you first taking them but not everyone will get it.

Tell your doctor or pharmacist if you notice the following side effects and it worries you:

- Dry mouth
- Constipation
- Blurring of vision
- Nausea
- Urinary hesitancy
- Palpitation
- Tachycardia
- Drowsiness
- Skin eruptions
- Changes in ECG (Electrocardiography) patterns
- Ataxia (unsteady movements)
- Confusion

*Tell your doctor or pharmacist if you notice anything else that make you feel unwell. Other side effects not listed above may also occur in some people.*

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## 7. HOW TO STORE TUMAX

Store in a cool, dry place below 30° C. Keep in original packaging to protect from light, heat and moisture.

Keep out of the reach of children.

### Disposal

Do not use Tumax after the expiry date which is stated on the carton or blister.

If your doctors tell you to stop taking Tumax or the expiry date has passed, ask your pharmacist the proper way to dispose the remaining medicines.

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## 8. PRODUCT DESCRIPTION

### What Tumax looks like and contents of the pack.

Tumax capsule is a green – green capsule with ‘SPS’ imprint.

Tumax capsule comes in strip of 10 tablets packed in box of 100 and 500 tablets and in bottle of 500 and 1000 tablets.

### What Tumax contains

The active ingredients are:

Chlordiazepoxide hydrochloride & Clidinium bromide

Each tablet contains:

Chlordiazepoxide hydrochloride 5.0 mg.  
Clidinium bromide 2.5 mg.

The other ingredients are:

*Talcum, Sodium Lauryl Sulfate, Spray dried rice starch, Croscarmellose Sodium, Colloidal Silicon Dioxide, Sodium Starch Glycolate, Magnesium Stearate, Crospovidone, Lactose Monohydrate.*

### Registration Number

MAL19962835A

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## 9. MARKETING AUTHORISATION HOLDER AND MANUFACTURER

### Marketing Authorization Holder:

IMEKS Pharma Sdn. Bhd.

No. 1 & 2, Jalan 6/33B,

MWE Commercial Park,

52000 Kuala Lumpur. Malaysia

### Manufactured by:

Sriprasit Pharma Co., Ltd.

619 Charoenrath Road,

Bangkok 10600,

Thailand.

**Tumax Capsule**

Chlordiazepoxide hydrochloride & Clidinium bromide

*Patient Information Leaflet*

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