

## PATIENT INFORMATION LEAFLET

### **THAROLAX (HYDROXYUREA / THAROLAX 100mg, 200mg, 300mg, 400mg, 500 mg Capsules USP)**

#### **Read all of this leaflet carefully before you start taking this medicine**

Keep this leaflet. You may need to read it again.

If you have any further questions, ask your doctor or pharmacist.

This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

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#### **IN THIS LEAFLET:**

1. What THAROLAX(Capsules) is and what it is used for
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#### **1. WHAT THAROLAX IS AND WHAT IT IS USED FOR**

The name of your medicine is THAROLAX. Each capsule contains Hydroxyurea as the active ingredient. Hydroxyurea belongs to a group of medicines called anti-neoplastic medicines. These medicines interfere with the growth of cancer cells.

THAROLAX is used to treat some types of cancer such as cervical cancer and a type of leukaemia called chronic myeloid leukaemia (CML). The precise reason why you are being given THAROLAX is best discussed with your doctor.

#### **2. BEFORE YOU TAKE THAROLAX**

##### **Do not take THAROLAX:**

- If you are allergic to hydroxyurea or any of the other ingredients of this medicine (listed in section 6).
- If you have history of any blood problems
- If you have severe anaemia

##### **Warnings and precautions**

Talk to your doctor or pharmacist before taking THAROLAX.

Your doctor will do regular blood tests before and whilst you are taking THAROLAX. You may need to control or treat the source conditions before starting treatment with THAROLAX.

##### **Take special care with THAROLAX if:**

- You have any kidney or liver problems
- You are pregnant, planning to become pregnant or are breast feeding
- You have ever suffered from gout
- You have leg ulcers
- You have previously received radiotherapy or chemotherapy, or are currently taking any other medicines for cancer treatment, especially interferon therapy
- You have folic acid deficiency

In long term use of THAROLAX, secondary leukaemia has been reported. Skin cancer has also been reported in patient receiving long term hydroxycarbamide. You should protect your skin from the sun, regularly inspect your skin yourself and be screened by your doctor for secondary malignancies during routine follow-up visits.

##### **Other medicines and THAROLAX**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, especially:

- Antiretroviral medicines (those that inhibit or destroy a retrovirus such as HIV), e.g., didanosine, stavudine and indinavir

- Myelosuppressive medicines (including chemotherapies) and radiation therapy

Always tell your doctor about other medicines you may be taking or have recently taken including those obtained without a prescription as some medicines can affect each others actions.

It may be necessary to adjust the dose of some medicines if they are taken at the same time as THAROLAX.

#### **THAROLAX with food, drink or alcohol**

You should check with your doctor before drinking alcohol to find out if it is advisable for you.

#### **Pregnancy and breast-feeding**

- You should not take this medicine if you are pregnant, planning to become pregnant or are breastfeeding, unless your doctor recommends it.
- When appropriate both male and female patients should discuss contraceptive measure before and during treatment with THAROLAX.
- In addition, if you are pregnant, planning to be or breastfeeding you should not handle the capsules.

#### **Driving and using machines**

- You may feel drowsy.
- You should not drive or operate any machinery unless it has been shown not to affect you and have discussed it with your doctor.

#### **THAROLAX contains lactose**

- If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

### **3. HOW TO TAKE THAROLAX**

- Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
- You may be instructed to take your medicine on either a daily basis or an irregular basis.
- The recommended dose is 20-30mg of THAROLAX per kg of your bodyweight once a day or 80 mg per kg of your body weight once every third day.
- Elderly patients may be more sensitive to the effects of THAROLAX and may be given a lower dose.
- You can take this medicine at any time of the day, before or after meals.
- The capsules should be swallowed whole with a glass of water. However if you find it difficult to swallow them, the contents of the capsule can be emptied into a glass of water and taken immediately. If some of the powder floats on the surface of the water, **DO NOT WORRY** this is just filler from the capsule.
- **DO NOT** inhale the contents of the capsules and if you spill any on the skin wipe it immediately.
- While you are being treated with THAROLAX it is important that you drink plenty of fluids. This will help your kidneys work well.
- If you are going to have radiation therapy, this medicine will usually be started 7 days before starting radiation treatment.
- You should keep taking your capsules until your doctor tells you to stop.

#### **Children**

There is limited experience with the use of THAROLAX in this age group.

#### **If you take more THAROLAX than you should**

If you take too many capsules you should go to your nearest hospital Casualty Department

immediately and take the medicine carton with you. The symptoms of overdose include; soreness, swelling of hands and feet and redness of skin.

#### **If you forget to take THAROLAX**

- If you forget to take a dose of this medicine DO NOT take the missed dose at all. Take your next dose when it is due; DO NOT take a double dose to make up for a forgotten dose.
- If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

#### **4. POSSIBLE SIDE EFFECTS**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

#### **If you notice any of the following symptoms:**

- Swelling of the face, lips, tongue or throat
- itching or skin rashes
- Difficulty breathing
- Unexplained fever
- Chills or sore throat
- Breathing difficulties,
- Wasting of muscles and peeling of the skin and nails, you should stop taking the tablets and tell your doctor immediately as these may be signs of an allergic reaction.

#### **If you notice any of these symptoms you should see your doctor immediately.**

- Unexplained shortness of breath or cough with feverskin ulceration, especially with severe infection
- Blood disorders (reduction in white blood cells, red blood cells and platelets)
- Lower back pain or pain in your side
- Black tarry stools or blood in the stools
- Unusual bleeding or bruising
- Numbness or tingling of hands or feet

#### **The following side effects have been seen in some people:**

- Skin changes and muscle weakness (dermatomyositis) - you may experience symptoms such as muscle tenderness, muscle weakness or tiredness (especially when climbing stairs, walking or rising from a chair etc), a rash on the face, hands or other parts of the body (which in some cases maybe scaly, purple and raised).
- Absence or low amount of sperm in the semen (azoospermia or oligospermia).
- Loss of appetite
- Weakness, loss of energy
- Sickness, diarrhoea, constipation, abdominal pain
- Sores on the lips or mouth
- Difficulty or pain passing urine
- Skin problems may occur including rashes, darkening of the skin, peeling of the skin, purple raised patches of skin and redness. There may be a worsening of existing redness or discomfort in the skin or mucous membranes if you have had radiation treatment in the past.
- Temporary hair loss
- Kidney problems
- Skin cancer
- Problems with the flow of the bile (cholestasis), the bile which is made by the liver to aid in digestion of food may not flow properly. A build up of bile can cause itchiness, yellow skin, very dark urine and very pale stools
- Inflammation of the liver (hepatitis) which cause flu-like symptoms, including tiredness, loss of appetite, fever, aching, and feeling sick/being sick, pressure or pain below the right ribs and might also include yellowing of the skin or eyes.
- Drowsiness, dizziness, fits, confusion or hallucinations (seeing hearing or feeling things that are not there)
- Headache.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

#### **5. HOW TO STORE THAROLAX**

- Do not store your tablets above 25°C
- Store in the original package in order to protect from moisture.
- Do not use this medicine after the expiry date which is stated on the blister or carton after EXP. The expiry date refers to the last day of that month.
- Keep this medicine out of the sight and reach of children.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

#### **6. CONTENTS OF THE PACK AND OTHER INFORMATION**

##### **What THAROLAX contains**

The active substance is hydroxyurea.

The other ingredients are citric acid anhydrous, erythrosine (E127), gelatin, indigotine (E132), lactose monohydrate, magnesium stearate, sodium laurilsulfate, sodium phosphate, titanium dioxide (E171), yellow iron oxide (E172) (500mg capsules), FD&C Blue No. 1 and FD&C Green No. 3 (200 mg capsules); D&C Red No. 28, D&C Red No. 33, and FD&C Blue No. 1 (300 mg capsules); D&C Red No. 28, D&C Red No. 33, and D&C Yellow No. 10 (400 mg capsules).

##### **What THAROLAX looks like and contents of the pack**

- 200 mg opaque blue-green capsules, imprinted with black ink
- 300 mg opaque purple capsules, imprinted with black ink

- 400 mg opaque reddish-orange capsules, imprinted with black ink
- 500mg THAROLAX are pink, opaque capsules with green, opaque caps.

THAROLAX are packed in blister packs of 100 capsules.

##### **Manufactured By:**

TAJ PHARMACEUTICALS Ltd.  
Mumbai, INDIA

##### **Marketed By:**

TAJ PHARMA INDIA LTD.  
CRESCENT, SAHAR AIRPORT ROAD,  
MUMBAI, MAHARASHTRA 400059  
INDIA

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