

## PATIENT COUNSELLING INFORMATION

### **Rx Drotaverine Hydrochloride & Mefenamic Acid Tablets**

#### **Din<sup>®</sup>-M Tablet**

**Read the entire leaflet carefully before you start taking this medicine:**

- If you have any further questions, ask your doctor.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet.
- 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.

#### **1. What is Din<sup>®</sup>-M Tablet and what is it used for?**

Din<sup>®</sup>-M Tablet is a combination of Drotaverine hydrochloride and Mefenamic acid. Din<sup>®</sup>-M Tablet is indicated for abdominal pain and dysmenorrhea.

#### **2. What you need to know before you take Din<sup>®</sup>-M Tablet?**

*Before taking Din<sup>®</sup>-M Tablet tell your doctor if you have:*

- if you are allergic (hypersensitive) to Drotaverine hydrochloride and Mefenamic acid or any of the other ingredients of this medicine;
- if you are allergic to any other NSAIDs such as aspirin, ibuprofen or celecoxib;
- if you have an inflammatory bowel disease such as Crohn's disease or ulcerative colitis;
- if you have a history of gastrointestinal conditions such as bleeding in the stomach,
- peptic ulcer, gastritis;
- if you have severe heart, liver or kidney failure;
- if you are in the last trimester of pregnancy (more than 6 months pregnant);
- if you have had heart bypass surgery.

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

*Talk to your doctor before taking Din<sup>®</sup>-M Tablet if:*

- you are taking any other NSAIDs such as ibuprofen, diclofenac;
- you are taking any other anti-inflammatory medicines, including steroids such as prednisolone;
- you are taking medicines such as warfarin or clopidogrel, which are used to thin the blood;
- you are taking selective serotonin medicines such as paroxetine, which are
- antidepressants;
- you have liver or kidney problems, as your doctor may monitor their function before and during treatment;
- you are trying to become pregnant;
- you are elderly

- previously taking painkillers such as aspirin have given you an upset stomach, or you have a history of stomach or digestive tract problems. Patients taking Mefenamic acid can experience bleeding in the stomach or gut;
- you are going to have a major operation or have a bleeding disorder, as Mefenamic acid can affect how your blood clots (it can make you bleed more or for longer periods of time);
- you have or have a history of asthma, as it may cause difficulties in breathing;
- you have epilepsy;
- you have a disorder of the connective tissue, such as Systemic Lupus Erythematosus (SLE);
- you are dehydrated with symptoms of thirst, dry mouth, dry skin, dark urine, headache;
- you have problems with your heart, have previously had a stroke, or you think you may be at risk of these conditions (e.g. if you have diabetes, high blood pressure, are a smoker, or have high cholesterol). Your doctor may carry out additional monitoring.

Medicines such as Mefenamic acid may be associated with a small increased risk of stroke or heart attack. Any such risk is more associated with high doses, and prolonged treatment.

**Do not exceed** the recommended dose or treatment duration.

#### **Other medicines and Din<sup>®</sup>-M Tablet**

Tell your doctor if you are taking:

- levodopa (used to treat parkinson's disease)
- medicines which can increase the chances of bleeding in the stomach or gut, or increase the risk of getting ulcers such as:
  - medicines used to treat arthritis and inflammation (corticosteroids);
  - medicines used to thin the blood (anti-platelet drugs such as warfarin, aspirin, clopidogrel);
  - anti-depressant medicines such as paroxetine, which are selective serotonin reuptake inhibitors (SSRIs);
  - medicines which are anti-inflammatory, such as diclofenac, celecoxib;
- aspirin, used in some heart conditions to stop your blood from clotting;
- medicines used to treat high blood pressure, such as atenolol, ramipril, valsartan;
- water tablets (diuretics), or medicines for the heart, such as digoxin, diltiazem, sotalol;
- medicines used to treat diabetes, such as glibenclamide, glipizide;
- medicines used to suppress the immune system, such as ciclosporin, methotrexate, tacrolimus;
- medicines used to treat some types of depression, and mood swings, such as lithium;
- a medicine called mifepristone which has been taken within the last 12 days. This is usually prescribed via hospitals;
- quinolone or aminoglycoside antibiotics, used to treat infections;
- zidovudine, used for HIV;
- probenecid, used in special situations to protect the kidneys;
- medicines which bind to protein in the blood.

### ***Pregnancy, breast-feeding and fertility***

If you are pregnant or breast feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

#### **Pregnancy**

Din<sup>®</sup>-M Tablet passes to your unborn baby. During the first six months of pregnancy, it is not known how it can affect your unborn baby. Your doctor will help you decide whether or not to take Din<sup>®</sup>-M Tablet in the first six months of pregnancy.

Din<sup>®</sup>-M Tablet should not be taken in the last three months of pregnancy, as this may prolong its duration and delay the onset of labour. This could also lead to bleeding in the mother or unborn baby.

#### **Breast-feeding**

Din<sup>®</sup>-M Tablet passes into breast milk and can affect the baby. You should not breast-feed whilst taking Din<sup>®</sup>-M Tablet, unless advised by your doctor.

#### **Fertility**

If you are trying to become pregnant, do not take Din<sup>®</sup>-M Tablet as it may make getting pregnant more difficult. Speak to your doctor if you are trying to become pregnant or are having difficulties getting pregnant.

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

Din<sup>®</sup>-M Tablet may cause drowsiness, fatigue, dizziness or may affect your vision. If you experience any of these symptoms, you should not drive or operate machinery, or perform any tasks which may require you to be alert.

### **3. How to take Din<sup>®</sup>-M Tablet?**

Always use this medicine exactly as your doctor has told you.

The recommended dose for the fixed dose combination of Drotaverine hydrochloride & Mefenamic acid tablets is one tablet three times daily or as directed by the Physician.

**Method of administration:** For oral use only, preferably with or after food.

#### **If you take more Din<sup>®</sup>-M Tablet than you should**

This may harm your stomach and kidneys, and you may suffer from seizures (fits).

If you have taken more dose of this medicine, than you should, talk to your doctor, pharmacist or nearest hospital emergency department immediately. You may require medical attention. This is important even if you feel well.

#### **If you forget to take Din<sup>®</sup>-M Tablet**

Do not take a double dose to make up for a forgotten dose, as you would not substitute the missing amount, but you risk an overdosing. Continue the treatment according to the instructions.

If you have any further questions on the use of this medicine, ask your doctor.

#### 4. What are the possible side effects of Din<sup>®</sup>-M Tablet?

Like all medicines, this medicine can cause side effects, although not everybody gets them. Common side effects may include: Nausea, vomiting, abdominal pain, diarrhea, constipation, dyspepsia, dry mouth, heartburn.

This is not a complete list of side effects and others may occur. Call your doctor for medical advice about side effects.

#### 5. How to store Din<sup>®</sup>-M Tablet?

**Store protected from light & moisture, at a temperature not exceeding 30°C.**

Keep out of reach of children.

Do not use this medicine after the expiry date which is stated on the container. The expiry date refers to the last day of that month.

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*For further information please write to:*



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