

## PATIENT COUNSELLING INFORMATION

### <sup>Rx</sup> Drotaverine Hydrochloride and Aceclofenac Tablets

#### Din<sup>®</sup>-A 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>-A Tablet and what is it used for?**

Din<sup>®</sup>-A Tablet is a combination of Drotaverine hydrochloride and Aceclofenac. Din<sup>®</sup>-A Tablet is indicated for the treatment of colicky pain due to smooth muscle spasm.

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

***Before taking Din<sup>®</sup>-A Tablet tell your doctor:***

- if you are allergic (hypersensitive) to Drotaverine hydrochloride and Aceclofenac or any of the other ingredients of this medicine. If you are allergic to aspirin or any other NSAIDs (such as ibuprofen, naproxen or diclofenac).
- if you have taken aspirin or any other NSAIDs and experienced one of the following:
  - asthma attack causing tightness in the chest wheezing and difficulty breathing.
  - runny nose, itching and/or sneezing (irritation of the nose).
  - raised red circular patchy rash on the skin which may have felt itchy or like a sting or burn.
  - a severe allergic reaction known as anaphylactic shock. The symptoms may be life threatening and include difficulty breathing, wheezing, abdominal pain and vomiting.
- if you have a history of, suffer from, or suspect that you have a stomach ulcer or have vomited blood or passed blood in your faeces (black tarry stools).
- if you have severe kidney disease.
- if you have established heart disease and /or cerebrovascular disease e.g. if you have had a heart attack, stroke, mini-stroke (TIA) or blockages to blood vessels to the heart or brain or an operation to clear or bypass blockages.
- if you have or have had problems with your blood circulation (peripheral arterial disease).
- if you suffer from, or suspect that you have severe liver failure.
- if you suffer from bleeding or any type of blood clotting disorders.
- if you are pregnant (unless your doctor considers it essential for you to continue to take this medicine).

Din<sup>®</sup>-A Tablet is not recommended for use in children.

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

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

- if you suffer from any other form of kidney or liver disease.
- if you have any of the following disorders, as they may worsen:
  - Disorders of the stomach or gut/bowel
  - inflammatory bowel disease (ulcerative colitis)
  - chronic inflammatory bowel disease (Crohn's disease)
  - ulceration, bleeding or perforation of the stomach or bowel
- if you have, or have ever had problems with the circulation of the blood to your brain.
- if you suffer from asthma or any other breathing problems
- if you suffer from a rare inherited disorder known as porphyria
- if you smoke
- if you have diabetes
- if you have angina, blood clots, high blood pressure, raised cholesterol or other raised body fats such as triglycerides
- if you suffer from an autoimmune condition known as systemic lupus erythematosus or other connective tissue disorders
- if you are infected with chicken pox, the use of this medicine should be avoided because a rare serious infection of the skin may develop
- if you are recovering from major surgery
- if you are elderly (your doctor will prescribe you the lowest effective dose over the shortest duration).

Hypersensitivity reactions can occur and very rarely, very serious allergic reactions are appearing. The risk is higher in the first month of treatment. Aceclofenac should be stopped immediately at the first onset of symptoms such as tightness of the chest, breathing difficulties, fever, skin rashes, soreness of the skin lining the mouth and other mucous membranes causing ulcers, or any signs of hypersensitivity.

Medicines such as Aceclofenac may be associated with a small increased risk of heart attack ("myocardial infarction"). Any risk is more likely with high doses and prolonged treatment.

Do not exceed the recommended dose or duration of treatment.

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

Tell your doctor if you are taking:

- levodopa (used to treat parkinson's disease)
- medicines used to treat mental health problems like depression (selective serotonin-reuptake inhibitors (SSRIs) such as citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine and sertraline) or manic depression (lithium)
- medicines used to treat heart failure and irregular heart beats (cardiac glycosides such as digoxin)
- medicines used to treat high blood pressure (antihypertensives: ACE inhibitors such as enalapril, lisinopril; angiotensin II receptor antagonists such as losartan, candesartan; also hydralazine, methyldopa, clonidine, moxonidine, propranolol)
- medicines to treat infection (quinolone antibiotics such as ciprofloxacin, ofloxacin, levofloxacin moxifloxacin)

- drugs used to increase the rate of urine excretion (diuretics such as thiazides, furosemide, amiloride hydrochloride)
- medicines that stop blood clotting (anticoagulants) such as warfarin, heparin
- methotrexate which is used to treat cancer and autoimmune disorders such as arthritis and skin conditions
- mifepristone
- any steroids for the treatment of swelling and inflammation (glucocorticoids such as hydrocortisone, prednisolone,)
- medicines used to suppress the immune system after organ transplant (cyclosporin or tacrolimus)
- medicines used to treat HIV (zidovudine)
- medicines used to lower blood sugar levels in diabetes (antidiabetics such as glibenclamide, glicazide, tolbutamide)
- any other painkiller NSAID drugs (aspirin, ibuprofen, naproxen, COX-2 inhibitors such as celecoxib and etoricoxib)
- antiplatelet drugs such as clopidogrel.

### ***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**

Do not take Din<sup>®</sup>-A Tablet if you are pregnant or think you are pregnant. The safety of this medicine for use during pregnancy is not known. It is not recommended for use in pregnancy unless considered essential by your doctor.

#### **Breast-feeding**

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

#### **Fertility**

If you are trying to become pregnant, do not take Din<sup>®</sup>-A 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>-A Tablet may cause dizziness, drowsiness, vertigo, tiredness or any difficulty with your eyesight, 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>-A Tablet?**

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

The recommended dose of Din<sup>®</sup>-A Tablet is one tablet twice daily or as directed by the Physician.

**Method of administration:** Swallow the tablet whole with a glass of water. Do not crush or chew the tablets.

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

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>-A 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>-A 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, dizziness and increased liver enzymes in the blood.

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>-A Tablet?**

**Store in a dry place, protected from light and moisture.**

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.

**Date of revision:** April 26, 2022

*For further information please write to:*



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