

## **WHAT IS IN THIS LEAFLET**

- What DOLOWIN-SR is and what it is used for
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## **1. WHAT DOLOWIN-SR IS AND WHAT IT IS USED FOR**

Aceclofenac SR Tablets belongs to a group of medicines called non-steroidal anti-inflammatory drugs or NSAIDs. Aceclofenac SR Tablets is used for the relief of pain and inflammation in toothache, trauma, lumbago, osteoarthritis, rheumatoid arthritis and ankylosing spondylitis:

- Arthritis of the joints (osteoarthritis). This commonly occurs in patients over the age of 50 and causes the loss of the cartilage and bone tissue next to the joint.
- Autoimmune disease that causes chronic inflammation of the joints (rheumatoid arthritis).
- Arthritis of the spine which can lead to the fusion of the vertebrae (ankylosing spondylitis).

## **2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE DOLOWIN-SR**

### **Do not take Dolowin SR Tablets if;**

- If you are allergic to Aceclofenac or any of the other ingredients of Aceclofenac Tablets
- If you are pregnant (unless considered essential by your doctor).
- If aspirin or other NSAIDs have caused asthma, rhinitis (running nose) or urticaria (skin rash) or other allergic reaction.
- If you have a peptic ulcer (ulcer in your stomach or duodenum) or bleeding in your stomach, or have had two or more episodes of peptic ulcers, stomach bleeding or perforation.
- If you have severe kidney disease
- If you have severe heart disease
- If you have severe liver disease

### **Take special care with Aceclofenac SR Tablets**

Tell your doctor before taking Aceclofenac SR tablets if:

- You have ever experienced stomach discomfort or pain, vomiting of blood or heartburn after taking aspirin or other nonsteroidal anti-inflammatory drugs.
- You suffer from any other form of kidney or liver disease.
- You suffer from asthma or any other breathing problems.
- You have suffered from any blood-clotting problem (if you bleed easily).

You have recently undergone major surgery.

- You are breast-feeding.
- You are suffering from Crohn's disease (chronic inflammatory bowel disease) or ulcerative colitis (inflammatory bowel disease).
- You suffer from a blood disorder known as porphyria.
- You have heart problems, previous stroke or think that you might be at risk of these conditions (for example if you have high blood pressure, diabetes or high cholesterol or are a smoker) you should discuss your treatment with your doctor or pharmacist. Medicines such as Aceclofenac Tablets may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke.

**Taking other medicines:**

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

- Anticoagulants (drugs that alter the rate of blood clotting) like warfarin.
- Diuretics (drugs used to increase the rate of urine excretion) such as furosemide, hydrochlorothiazide or triamterene.
- Antidiabetic drugs (medicines used to lower blood sugar levels).
- Methotrexate (used to treat cancer, arthritis)
- Steroids.
- Ciclosporin and Tacrolimus (drugs used to suppress the immune system)
- Anti infective (Such as quinolone antibiotics)

**Taking Aceclofenac SR Tablets with food and drink:**

Aceclofenac SR Tablets should be taken preferably with or after food.

**Pregnancy and breast-feeding:**

Since there is no information on the safe use of Aceclofenac SR during pregnancy and lactation, the use of Aceclofenac SR should therefore be avoided in pregnancy and lactation. The dosage and indication is not yet established for children less than 6 years old.

**Driving and using machines:**

As a precaution, you should refrain from driving or operating machinery if you feel dizzy or sleepy when you take Aceclofenac Tablets. Do not perform any of these actions until the effects wear off.

**3. HOW TO TAKE DOLOWIN-SR**

Always take Aceclofenac SR Tablets exactly as your doctor has told you. You will be prescribed the lowest effective dose over the shortest duration to reduce side effects. You should check with your doctor or pharmacist if you are not sure.

**Adults:**

Adults: The recommended dose is 200 mg daily, taken as one dose (every 24 hours). Or as prescribed by the physician.

**Children:**

Aceclofenac SR Tablets is not recommended for use in children under the age of 18.

**Elderly**

If you are elderly, you are more likely to experience serious side effects. If your doctor prescribes Aceclofenac SR Tablets for you, you will be given the lowest effective dose over the shortest duration.

**Method and route of administration:**

Swallow the tablet whole with a glass of water. Do not crush or chew the tablets. Never change the dose of your medicine without talking to your doctor first. Continue to take your tablets for as long as your doctor recommends.

**If you take more Aceclofenac SR Tablets than you should:**

If you take more Aceclofenac SR tablets than you have been told to take, or if someone else accidentally takes your medicine, immediately see a doctor or go to a hospital straight away.

**If you forget to take Aceclofenac SR Tablets:**

If you forget to take your medicine at any time, take it as soon as you remember; then continue to take it at the usual times. Do not take a double dose to make up for a forgotten dose.

**If you stop taking Aceclofenac SR Tablets:**

Do not stop taking your tablets even if you are feeling well, unless your doctor tells you. If you have any further question on the use of the product, ask your doctor or pharmacist.

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

Like all medicines, Aceclofenac SR tablets can cause side effects, although not everybody gets them. If you experience any of the following side effects, tell your doctor IMMEDIATELY:

- medicines such as Aceclofenac SR tablets may be associated with a small increased risk of heart attack, ("myocardial infarction") or stroke
- Severe allergic reaction (anaphylactic shock). Symptoms may include difficulty breathing, wheezing, abnormal pain and vomiting
- swelling of the face
- kidney failure

If you suffer from any of the following at any time during your treatment STOP TAKING the medicine and seek immediate medical help:

- Pass blood in your faeces (stools/motions)
- Pass black tarry stools
- Vomit any blood or dark particles that look like coffee grounds.

#### **STOP TAKING the medicine and tell your doctor if you experience:**

- Indigestion or heartburn
- Abdominal pain (pains in your stomach) or other abnormal stomach symptoms.

If any of the below side effects get serious, or if you notice any other side effects not listed in this leaflet, please tell your doctor or pharmacist. Common (occur in more than 1 in 100 patients but in less than 1 in 10 patients):

- dizziness
- nausea (feeling sick)
- diarrhoea
- increased liver enzymes in the blood

Uncommon (occur in more than 1 in 1,000 patients but in less than 1 in 100 patients):

- wind (flatulence)
- inflammation or irritation of the lining of the stomach (gastritis)
- constipation
- vomiting
- mouth ulcers
- itching
- rash
- inflammation of the skin (dermatitis)
- raised circular red itchy, stinging or burning patches on the skin (hives)
- increase in blood urea levels
- increase in blood creatinine levels

Rare (occur in more than 1 in 10,000 patients but in less than 1 in 1,000 patients):

- low levels of iron in the blood
- hypersensitivity (allergic reaction)
- visual disturbance
- shortness of breath

Very rare (occur in less than 1 in 10,000 patients):

- low white blood cells levels
- low platelets levels in the blood
- abnormal breakdown of red blood cells (anaemia)
- high potassium levels in the blood
- depression
- strange dreams
- inability to sleep
- tingling, pricking or numbness of skin
- uncontrollable shaking (tremor)
- drowsiness

- headaches
- abnormal taste in the mouth
- sensation of spinning when standing still
- heart pounding or racing (palpitations)
- hot flushes
- difficulty breathing
- high pitched noise when breathing
- inflammation of the mouth
- stomach ulcer
- inflammation of the pancreas (pancreatitis)
- inflammation of the liver (hepatitis)
- yellowing of the skin (jaundice)
- spontaneous bleeding into the skin (appears as a rash)
- blisters
- water retention and swelling
- tiredness
- leg cramps
- increased blood alkaline phosphatase levels
- weight gain

## **5. HOW TO STORE DOLOWIN-SR**

Keep out of the reach and sight of children.

- Store below 30°C.
- Do not use the medicine after the expiry date, which is stated on the carton after (EXP). The expiry date refers to the last day of that month.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

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

*What Dolowin-SR contains,*

Each film coated sustain release tablets contains: Aceclofenac BP Tablets .....200 mg

*What Dolowin-SR looks like and contents of the pack*

Pink coloured circular, biconvex film- coated sustained release tablets plain on both sides.

10 Tablets are packed in a Alu/Alu Blisters pack. Such 3 blister Is packed in a carton along with pack insert.

### **Manufacturer**

**MICRO LABS LIMITED**

92, SIPCOT,

HOSUR-635 126, INDIA

### **Marketing Authorisation Holder**

**MICRO LABS LIMITED**

27, Race course road

Bangalore-560001

### **Date of Revision**

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