



### **WHAT IS IN THIS LEAFLET**

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

Dolowin – Plus contains Aceclofenac & Paracetamol as the active ingredients.

- Aceclofenac belongs to a group of medicines called non-steroidal anti-inflammatory drugs or NSAIDs.
- Paracetamol is a clinically proven analgesic and antipyretic agent with weak anti-inflammatory effect. It works by relieving pain and reducing high temperature and fever.

Dolowin – Plus is indicated for relief from severe pain and inflammation in Osteoarthritis, Rheumatoid arthritis, Ankylosing spondylitis, Low back pain, Dental pain, Gynaecological pain and painful & Inflammatory conditions of ear, nose & throat.

### **WHAT YOU NEED TO KNOW BEFORE YOU TAKE DOLOWIN- PLUS**

#### **Do not take Aceclofenac & Paracetamol Tablets**

- If you are allergic to Aceclofenac or Paracetamol or any of its ingredients.
- If you are taking any other products that contain Paracetamol.
- 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, liver and heart disease.

#### **Take special care with Aceclofenac & Paracetamol Tablets**

Tell your doctor before taking Aceclofenac and Paracetamol 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. Or G-6-PD deficiency (an hereditary condition leading to low red blood cell counts).
- You suffer from asthma or any other breathing problems.
- You have suffered from any blood- clotting problem (if you bleed easily).

#### **Taking Aceclofenac & Paracetamol Tablets using 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-infectives (Such as quinolone antibiotics)
- Zidovudine (drug used to treat HIV)
- Cardiac glycosides like digoxin (used to treat heart failure and irregular heartbeats).
- Do not use this medicine if you are taking medicines that reduce the clotting of the blood (e.g. warfarin).

Talk to your doctor or a pharmacist if you are taking some antibiotics (chloramphenicol), anti-sickness treatments (metoclopramide, domperidone), some treatments for diarrhoea caused by gall bladder disease, or lipid lowering drugs (cholestyramine).

### **Taking Aceclofenac & Paracetamol Tablets with food and drink**

Aceclofenac Tablets should be taken preferably with or after food.

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

Do not take Aceclofenac Tablets if you plan to become pregnant, are pregnant or breast-feeding.

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

### **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- PLUS**

Always take Aceclofenac & Paracetamol Tablets exactly as your doctor has told you.

The recommended dose of Dolowin – Plus is 1 tablet twice daily.

### ***Method 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 & Paracetamol Tablets than you should**

If you take more Aceclofenac 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 & Paracetamol 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 & Paracetamol 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**

### ***Aceclofenac***

Like all medicines, Aceclofenac 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 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 (anemia)
- 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.

If any of the below side effects get serious, please tell your doctor or pharmacist.

Other side effects that have been reported with this type of drug (NSAIDs) are:

- Bone marrow failure
- Hallucinations
- Confusion
- blurred, partial or complete loss of vision
- Painful movement of the eye
- ringing in the ears
- aggravated asthma
- Ulcers
- Perforation of either the stomach, large intestine or bowel wall
- blistering and peeling of the top layer of skin
- mild, itchy pink/redness of the skin
- reddening or scaling of skin
- Skin irritation (eczema)
- Skin reaction to sunlight
- Inflammation of the kidneys
- Generally feeling unwell
- Aseptic meningitis
- Exacerbation of colitis and Crohn's disease
- Hypertension (high blood pressure)
- Cardiac failure
- Bone marrow depression

### ***Paracetamol***

Like all medicines, your medicine can cause side effects, although not everybody gets them. You can reduce the chances of experiencing side effects by using the minimum dose required. Side effects may be more serious in the elderly patients.

If you experience any of the following serious effects STOP taking this medicine immediately and contact your doctor or pharmacist:

- Severe allergic reactions: difficulty breathing, skin rash, swollen facial features or a runny nose.

### ***Other possible side effects***

If any of the following side effects get serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist:

- Occasionally the blood does not clot well, which may result in easy bruising or bleeding.
- Rarely, a severe reduction in the number of white blood cells, which makes infections more likely.

- Other rare side effect like shortness of breath.

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

Keep out of the reach and sight of children.

- Store below 30°C. Keep all medicine away from the reach of children.
- 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- PLUS contains,*

Each film-coated tablet contains: Aceclofenac BP 100 mg and Paracetamol BP 500mg

*What DOLOWIN- PLUS looks like and contents of the pack*

White, Oblong shaped film-coated tablets with a breakline on one surface.

Alu/PVC blister pack of 1 x10's

### **Manufacturer**

**MICRO LABS LIMITED**

92, SIPCOT,

HOSUR-635 126, INDIA

### **Marketing Authorisation Holder**

**MICRO LABS LIMITED**

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INDIA

### **Date of Revision**

July 2019