

## **Package leaflet: Information for the user**

### **Miofen 600 mg film-coated tablets** ibuprofen

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- 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. It includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet**

1. What Miofen is and what it is used for
2. What you need to know before you take Miofen
3. How to take Miofen
4. Possible side effects
5. How to store Miofen
6. Contents of the pack and other information

#### **1. What Miofen is and what it is used for**

Miofen belongs to a group of medicines called NSAIDs (non-steroidal anti-inflammatory drugs). Miofen reduces fever, relieves pain and has an anti-inflammatory effect.

Miofen is used for rheumatic conditions such as rheumatic arthritis, and arthrosis in adults and adolescents (12-18 years old, 40 kg and above).

#### **2. What you need to know before you take Miofen**

##### **Do not take Miofen:**

- if you are allergic to ibuprofen or any of the other ingredients of this medicine (listed in section 6)
- if you are in the last three months of pregnancy
- if you have an increased tendency to bleed
- if you have severe liver and kidney disease
- if you have severe heart failure
- if you have a stomach ulcer, duodenal ulcer or bleeding, or if you have had a stomach ulcer, duodenal ulcer or bleeding previously when treated with Miofen or a similar product.
- if you have ever had bleeding or a tear in your stomach or gut when taking NSAIDs
- if you have experienced allergic reactions (e.g. breathing difficulties, nasal obstruction, rash) to acetylsalicylic acid or other anti-inflammatory drugs.
- if you are a child or adolescent below 12 years of age

#### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Miofen:

- if you have certain disorders of the immune system (mixed connective tissue disorders and systemic lupus erythematosus (SLE), conditions of the immune system affecting connective tissue resulting in joint pain, skin change and disorders of other organs) as there may be an increased risk of aseptic meningitis
- if you have impaired kidney or liver function
- if you have heart problems including heart failure, angina (chest pain), or if you have had a heart attack, bypass surgery, peripheral artery disease (poor circulation in the legs of feet due to narrow or blocked arteries), or any kind of stroke (including ‘mini-stroke’ or transient ischaemic attack “TIA”)
- if you have high blood pressure, diabetes, high cholesterol, have a family history of heart disease or stroke, or if you are a smoker
- if you have asthma, chronic rhinitis (chronic stuffy and runny nose) or allergic diseases since Miofen can cause difficulty breathing, hives or a serious allergic reaction when you have any of these conditions
- if you have inflammatory bowel diseases, previous stomach ulcer or other increased tendency to bleed
- if you have an infection - please see heading “Infections” below.

Serious skin reactions including exfoliative dermatitis, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS), acute generalized exanthematous pustulosis (AGEP) have been reported in association with ibuprofen treatment. Stop using Miofen and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

Always aim for the lowest possible dose and shortest possible treatment time to reduce the risk of side effects. It is generally the case that higher than recommended doses can entail risks. This also means that the combination of several NSAID products at the same administration time should be avoided. If you use painkillers for a long time, this can cause headaches, which should not be treated with more painkillers. If you think this applies to you, talk to your doctor or pharmacist.

Patients who have previously had gastrointestinal tract problems, especially elderly patients, should contact a doctor in the event of abdominal symptoms, (especially gastrointestinal bleeding) particularly at the start of treatment.

Elderly patients should be aware of their increased risk of adverse events, especially bleeding and perforation in the digestive tract, which may be fatal.

Treatment must be stopped and a doctor consulted when gastrointestinal bleeding or ulceration occurs during treatment with Miofen.

Anti-inflammatory/pain-killer medicines like ibuprofen may be associated with a small increased risk of heart attack or stroke, particularly when used at high doses. Do not exceed the recommended dose or duration of treatment

This product belongs to a group of medicines (NSAIDs) which may impair the fertility in women. This effect is reversible on stopping the medicine. See also section “Pregnancy, breast-feeding and fertility”.

Do not take Miofen if you are planning a pregnancy. Consult your doctor first. See also section 2, “Pregnancy, breast-feeding and fertility”.

**Stop taking Miofen and contact a doctor immediately** if you develop any of the following symptoms (angioedema)

- swelling of the face, tongue or throat,

- difficulties swallowing,
- hives and difficulties breathing.

Serious skin reactions have been reported in association with Miofen treatment. You should stop taking Miofen and seek medical attention immediately, if you develop any skin rash, lesions of the mucous membranes, blisters or other signs of allergy since this can be the first signs of a very serious skin reaction. See section 4.

Miofen may cause a reduction in the number of white blood cells and your resistance to infection may be decreased. If you experience an infection with symptoms such as fever and serious deterioration of your general condition, or fever with local infection symptoms such as sore throat/pharynx/mouth or urinary problems you should see your doctor immediately. A blood test will be taken to check possible reduction of white blood cells (agranulocytosis). It is important to inform your doctor about your medicine.

Caution should be exercised with regards to dehydrated patients, as there is a risk of renal impairment, especially in dehydrated children, adolescents and the elderly.

### Infections

Miofen may hide signs of infections such as fever and pain. It is therefore possible that Miofen may delay appropriate treatment of infection, which may lead to an increased risk of complications. This has been observed in pneumonia caused by bacteria and bacterial skin infections related to chickenpox. If you take this medicine while you have an infection and your symptoms of the infection persist or worsen, consult a doctor without delay.

During chicken pox (varicella) it is advisable to avoid use of this drug.

Signs of an allergic reaction to this medicine, including breathing problems, swelling of the face and neck region (angioedema), chest pain have been reported with ibuprofen. Stop immediately Miofen and contact immediately your doctor or medical emergencies if you notice any of these signs.

### **Children and adolescents**

There is a risk of renal impairment in dehydrated children and adolescents.

Miofen 600 mg tablets should not be taken by children and adolescents under 12 years of age or below 40 kg.

### **Other medicines and Miofen**

Do not use different types of pain-relieving medicines at the same time unless directed by a doctor.

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

Miofen may affect or be affected by some certain medicines, including medicines to treat/prevent:

- thromboembolic disorders (medicines that are anti-coagulants i.e. thin blood/prevent clotting e.g. aspirin/acetylsalicylic acid, dicumarol, warfarin, ticlopidine)
- high blood pressure (e.g. ACE-inhibitors such as captopril, beta-blockers such as atenolol medicines, angiotensin-II receptor antagonists such as losartan, diuretics)
- tumours and immune system disorders (methotrexate),
- manic depressive illness (lithium),
- irregular heart beat (digoxin),
- pain (acetylsalicylic acid),
- depression (medicines called SSRIs – selective serotonin reuptake inhibitors),

- rejection in patients receiving organ transplants (medicines that suppress your immune system, such as ciclosporine or tacrolimus)
- inflammation (corticosteroids),
- fungal infections (antifungals particularly voriconazole or fluconazole),
- bacterial infections (some antibiotics including aminoglycosides),
- diabetes mellitus (sulphonylureas),
- high cholesterol (cholestyramine
- human immunodeficiency virus (HIV) infection (zidovudine or ritonavir),

Some other medicines may also affect or be affected by the treatment of Miofen. You should therefore always seek the advice of your doctor or pharmacist before you use Miofen with other medicines.

#### **Miofen with food, drink and alcohol**

Miofen could be used together with food and drinks. Miofen can be given on an empty stomach for faster relief. If Miofen is taken together with alcohol, side effects may be increased.

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

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

##### *Pregnancy*

Do not take Miofen if you are in the last 3 months of pregnancy as it could harm your unborn child or cause problems at delivery. It can cause kidney and heart problems in your unborn baby. It may affect your and your baby's tendency to bleed and cause labour to be later or longer than expected. You should not take Miofen during the first 6 months of pregnancy unless absolutely necessary and advised by your doctor. If you need treatment during this period or while you are trying to get pregnant, the lowest dose for the shortest time possible should be used. If taken for more than a few days from 20 weeks of pregnancy onward, Miofen can cause kidney problems in your unborn baby that may lead to low levels of amniotic fluid that surrounds the baby (oligohydramnios) or narrowing of a blood vessel (ductus arteriosus) in the heart of the baby. If you need treatment for longer than a few days, your doctor may recommend additional monitoring.

##### *Breast-feeding*

Ibuprofen passes into breast milk. The use of ibuprofen is therefore not recommended while breastfeeding. However, consult a doctor if using ibuprofen more than occasionally while breastfeeding is required.

##### *Fertility*

The use of ibuprofen may affect fertility. The use of ibuprofen is not recommended while attempting to conceive or during investigation of infertility.

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

Miofen may impair reactions in some people, for example due to side effects such as visual disturbances, dizziness or drowsiness. This should be taken into consideration on occasions when high alertness is required, e.g. driving, and applies to a greater extent in combination with alcohol.

#### **Miofen contains lactose monohydrate**

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 Miofen:**

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The lowest effective dose should be used for the shortest duration necessary to relieve symptoms. If you have an infection, consult a doctor without delay if symptoms (such as fever and pain) persist or worsen (see section 2).

The recommended dose is:

Adults and adolescents over 12 years (over 40 kg)

*Rheumatic conditions*

One 600 mg tablet 3 times daily. Allow 4-6 hours between doses. For faster relief of stiffness in the morning, the first dose can be given on an empty stomach.

In adolescents the recommended dose is 20 mg/kg to a maximum of 40 mg/kg body weight daily in 3 to 4 doses. These tablets may not be suitable for this age and body weight group since they may contain a higher level of ibuprofen in one tablet than is appropriate. Your doctor will advise you accordingly.

The maximum daily dose shall not exceed 4 tablets (2400 mg).

To help prevent a passing feeling of a burning sensation in the throat or mouth, the tablets should be swallowed whole with at least half a glass of water. For a faster onset of action, Miofen may be taken on empty stomach. If you have a sensitive stomach, the tablet is preferably taken with or after food.

If you have severe liver and kidney disease or are elderly your doctor will tell you the correct dose to take which will be the lowest dose possible.

**If you take more Miofen than you should**

If you have taken more Miofen than you should, or if children have been taken medicine by accident always contact a doctor or hospital to get an opinion of the risk and advice on action to be taken.

The symptoms can include nausea, stomach pain, vomiting (may be blood streaked), headache, ringing in the ears, confusion and shaky eye movement. At high doses, drowsiness, chest pain, palpitations, loss of consciousness, convulsions (mainly in children), weakness and dizziness, blood in urine, cold body feeling, and breathing problems have been reported.

**If you forget to take Miofen**

Do not use a double dose to make up for a forgotten dose.

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

**4. Possible side effects**

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

*Most serious side effects*

**Stop taking Miofen and contact a doctor immediately** if you develop any of the following symptoms (angioedema an uncommon side effect)

- swelling of the face, tongue or throat,
- difficulties swallowing,
- hives and difficulties breathing.

Miofen may cause a reduction in the number of white blood cells (agranulocytosis) with decreased resistance to infection (an uncommon side effect). You should see your doctor immediately if you experience an infection with symptoms such as fever and serious deterioration of your general

condition, or fever with local infection symptoms such as sore throat/pharynx/mouth or urinary problems. It is important to inform your doctor about your medicine.

Serious skin and mucous membrane changes such as epidermal necrolysis and/or erythema multiforme have been reported (a very rare side effect). In addition, a severe skin reaction known as DRESS syndrome can occur. Symptoms of DRESS include: skin rash, fever, swelling of lymph nodes and an increase of eosinophils (a type of white blood cells). **Stop taking Miofen and contact a doctor** if you develop a rash or mucous membrane lesions. The severe rashes may include blisters on the skin, especially on the legs, arms, hands and feet which can also involve the face and lips. This can get even more severe, where the blisters get larger and spread out and parts of the skin may slough off (toxic epidermal necrolysis). There may also be severe infection with destruction (necrosis) of skin, subcutaneous tissue and muscle. These serious skin rashes can be preceded by fever and flu-like symptoms.

A red, scaly widespread rash with bumps under the skin and blisters mainly localized on the skin folds, trunk, and upper extremities accompanied by fever at the initiation of treatment (acute generalised exanthematous pustulosis). Stop using Miofen if you develop these symptoms and seek medical attention immediately. See also section 2. The frequency of these side effects is not known.

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

*Common* (may affect up to 1 in 10 people)

- Headache
- lightheadedness
- Gastrointestinal side effects (indigestion, diarrhoea, nausea, vomiting, abdominal pain, flatulence, constipation, black stools, bleeding in stomach and intestine, vomiting blood)
- Rash.
- Tiredness.

*Uncommon* (may affect up to 1 in 100 people)

- Rhinitis,
- Hypersensitivity
- Insomnia,
- anxiety
- Visual disturbances
- hearing impairment
- Bronchial spasm, asthma
- Mouth ulceration
- Stomach ulcer, intestinal ulcer, ruptured stomach ulcer, inflammation of mucous membrane of stomach
- Hepatitis,
- jaundice, abnormal liver function.
- Itching, small bruises in skin and mucous membranes
- Photosensitivity.
- Impaired kidney function.
- Changes in blood count
- Anaemia (a reduction in red blood cells or hemoglobin, which can make the skin pale and may lead to weakness)
- Drowsiness
- Tingling sensation.
- Hearing loss

*Rare* (may affect up to 1 in 1,000 people)

- Non-bacterial meningitis
- Allergic reaction
- Depression,
- confusion
- Impaired vision,
- tinnitus (ringing in ears), dizziness
- Liver damage and fluid retention in body.

*Very rare* (may affect up to 1 in 10,000 people)

- Inflammation of the pancreas
- liver failure

*Not known:* (frequency cannot be estimated from the available data)

- Worsening of ulcers in the large intestine (colitis) and Crohn's Disease (bowel disease)
- Heart failure, heart attack, high blood pressure
- Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome

Please note that Miofen can prolong bleeding time.

Exceptionally, serious infections of the skin in case of chicken pox (varicella).

When an NSAID is used, an infection-related inflammation of the skin could develop or become more severe (e.g. a condition such as necrotising fasciitis may develop characterized by intense pain, high fever, swollen and hot skin, blistering, necrosis). If signs of an infection of the skin occur or get worse during use of Ibuprofen you are recommended to see your doctor immediately.

Medicines like Miofen may entail a slightly increased risk of heart attack or stroke.

### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V\*. By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Miofen**

Keep this medicine out of the sight and reach of children.

Do not store above 30°C.

Do not use this medicine after the expiry date which is stated on the bottle, blister or carton after EXP. The expiry date refers to the last day of that month.

After first opening of the tablet container the product should be used within 12 months

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 Miofen contains**

One tablet contains 600 mg ibuprofen

- The active substance is ibuprofen.
- The other ingredients are: maize starch, microcrystalline cellulose, croscarmellose sodium, anhydrous colloidal silica, stearic acid, sodium lauryl sulfate, povidone (K-30), talc, hypromellose (2910, E 464)lactose monohydrate, triacetin and titanium dioxide (E 171)

**What Miofen looks like and contents of the pack**

White coloured, capsule shaped, 19 x 8.8 mm, biconvex, film coated tablets, plain on both sides

600 mg:

Blister: 10, 20, 24, 30 film-coated tablets

Bottle: 24, 30, 100, 250 film-coated tablets

Not all pack sizes may be marketed.

**Marketing Authorisation Holder**

Alter Pharma  
Square Marie Curie 50  
1070 Anderlecht  
Belgium

**Manufacturer(s)**

SANTA S.A.  
Address: Str. Panselelor, nr. 25, nr. 27, nr. 29,  
Brasov, jud. Brasov,  
Cod 500419, Romania

**This medicinal product is authorised in the Member States of the EEA under the following names:**

Sweden Ibuprofen 2care4  
Ireland Miofen 600mg Film-coated Tablets

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