

**PACKAGE LEAFLET**

## Package leaflet: Information for the user

### Abfen 600 mg Effervescent Granules 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. This includes any possible side effects not listed in this leaflet. See section 4.

#### What is in this leaflet

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

The full name of your medicine is **Abfen 600 mg Effervescent Granules**. In this leaflet the shorter name Abfen is used.

#### 1. What Abfen is and what it is used for

Abfen belongs to a group of medicines called ‘non-steroidal anti-inflammatory drugs’ or NSAIDs. Each sachet of medicine contains 600 mg ibuprofen.

This medicine is used:

- to relieve pain and inflammation in conditions such as osteoarthritis, rheumatoid arthritis, arthritis of the spine (ankylosing spondylitis), swollen joints, frozen shoulder, bursitis, tendinitis, tenosynovitis, lower back pain, sprains and strains.
- to treat other painful conditions such as toothache, pain after operations, period pain and headache, including migraine.

#### 2. What you need to know before you take Abfen

##### Do not take Abfen if:

- you are allergic to ibuprofen or any of the other ingredients of this medicine (listed in section 6)
- you have ever had an allergic reaction to ibuprofen, acetylsalicylic acid (e.g. Aspirin) or other NSAIDs - the signs include a reddening or rash of the skin, swollen face or lips or shortness of breath or stuffy and runny nose (rhinitis)
- you have ever had bleeding or a tear in your stomach or gut when taking other NSAIDs
- you have had two or more episodes of a stomach ulcer (peptic ulcer) or bleeding in your stomach or gut
- you have an illness that may make you more likely to bleed

- you have severe liver or kidney problems
- you have severe heart failure or coronary heart disease
- you are in the last 3 months of pregnancy. See ‘Pregnancy, breast-feeding and fertility’ below for more information.

### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Abfen.

#### **Heart attack and stroke**

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.

You should discuss your treatment with your doctor or pharmacist before taking Abfen 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”).
- have high blood pressure, diabetes, high cholesterol, have a family history of heart disease or stroke, or if you are a smoker.

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 Abfen and contact immediately your doctor or medical emergencies if you notice any of these signs.

#### **Gastrointestinal bleeding, ulceration or perforation**

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.

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

#### **General information on prolonged use of painkillers**

In general the habitual use of (several sorts of) analgesics can lead to lasting severe kidney problems. This risk may be increased under physical strain associated with loss of salt and dehydration. Therefore it should be avoided.

Prolonged use of any type of painkiller for headaches can make them worse. If you think this applies to you stop taking this medication or any other painkillers and talk to your doctor or pharmacist.

#### **Renal effects**

There is a risk of renal impairment in dehydrated patients (especially in children, adolescents and the elderly).

#### **Skin reactions**

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 Abfen and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

### **Infections**

Abfen may hide signs of infections such as fever and pain. It is therefore possible that Abfen 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.

### **Tell your doctor if you :**

- have or have had asthma (difficulty breathing), chronic rhinitis (chronic stuffy and runny nose) or allergic reactions (hives)
- have kidney, heart or liver problems
- have ever had stomach or gut problems (such as ulcerative colitis or Crohn's disease)
- have Systemic lupus erythematosus (SLE, an illness that affects connective tissue, including your joints and skin) or other autoimmune diseases because of increased risk of aseptic meningitis (stiff neck, headache, nausea, vomiting, fever or disorientation)
- are in the first 6 months of pregnancy
- are planning to become pregnant
- are elderly (65 years and above) - this is because you may be more likely to get serious side effects, especially bleeding and perforation in the digestive tract, which may be fatal
- have an infection - please see heading "Infections" above.

Talk to your doctor or pharmacist before taking Abfen if any of the above applies to you.

### **Children and adolescents**

Abfen is not suitable for children and adolescents under 18 years of age.

If you are taking Abfen for longer than the recommended time or at higher than recommended doses you are at risk of serious harms. These include serious harms to the stomach/gut and kidneys, as well as very low levels of potassium in your blood. These can be fatal (see section 4).

### **Other medicines and Abfen**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because Abfen may affect or be affected by some other medicines. For example:

- medicines that are anti-coagulants (i.e. thin blood/prevent clotting e.g. aspirin/acetylsalicylic acid, warfarin, ticlopidine)
- medicines that reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol medicines, angiotensin-II receptor antagonists such as losartan)

In particular you should tell your doctor or pharmacist if you are taking any of the following medicines in addition to those above.

- diuretics (water tablets)
- cardiac glycosides such as digoxin (used to treat heart conditions)
- lithium (used to treat certain forms of depression)
- phenytoin (used in the treatment of epilepsy)
- zidovudine (an anti-viral drug)
- probenecid (used in the treatment of gout)

- steroids (used in the treatment of inflammatory conditions)
- methotrexate (used to treat certain cancers)
- medicines known as immunosuppressants such as ciclosporin and tacrolimus (used to dampen down your immune response)
- medicines known as selective serotonin reuptake inhibitors (SSRIs) (used for the treatment of depression)
- antibiotics called quinolones such as ciprofloxacin
- aminoglycosides (a type of antibiotic)
- mifepristone (used for medical termination of pregnancy)
- any other ibuprofen preparations, such as those you can buy without a prescription
- any other anti-inflammatory pain killer including acetylsalicylic acid (e.g. Aspirin)
- cholestyramine (a drug used to lower cholesterol)
- medicines known as sulphonylureas such as glibenclamide (used to treat diabetes)
- voriconazole or fluconazole (types of anti-fungal drugs)
- ginkgo biloba herbal medicine (there is a chance you may bleed more easily if you are taking this with ibuprofen).

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

#### **Abfen with alcohol**

If you drink alcohol while taking this medicine you may be more likely to get side effects.

#### **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 or pharmacist for advice before taking this medicine.

- Do not take this medicine 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.
- Talk to your doctor or pharmacist before taking this medicine if you are in the first 6 months of pregnancy or you are breast-feeding. You should only take this medicine on the advice of your doctor. You should not take Abfen 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, Abfen 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.
- Tell your doctor or pharmacist before taking this medicine if you are planning to become pregnant or if you are having problems getting pregnant. This is because this medicine may make it more difficult to get pregnant when used over a long period of time. However, it is unlikely that using this medicine occasionally will affect your chances of getting pregnant. This effect usually goes away when you stop taking the medicine.

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

This medicine may make you feel dizzy or sleepy. If this happens, do not drive or use any tools or machines. Also, do not do anything else where you need to be alert. This particularly applies in combination with alcohol.

**Abfen contains sucrose**

Sucrose is a sugar. If you have been told by your doctor that you cannot tolerate or digest some sugars, talk to your doctor before taking this medicine. Each sachet contains 3.3 g sucrose. This should be taken into account in patients with diabetes mellitus.

**Abfen contains sodium**

This medicine contains 197 mg sodium (main component of cooking/table salt) in each sachet. This is equivalent to 9.9% of the recommended maximum daily dietary intake of sodium for an adult. Talk to your doctor or pharmacist if you need 2 or more sachets daily for a prolonged period, especially if you have been advised to follow a low salt (sodium) diet.

**3. How to take Abfen**

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

The product is intended for short-term use only. 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 ).

**How much to take****Adults (of 18 years and older):**

- The recommended dose is 1 sachet (600 mg) taken two or three times a day.
- Your doctor may choose to increase or decrease this depending on what you are being treated for. Do not take more than 4 sachets (2,400 mg) in any 24 hours.

**Children and adolescents:**

Abfen is not recommended for children and adolescents under 18 years of age.

**People with liver or kidney problems:**

If you have liver or kidney problems, your doctor will tell you the correct dose to take. This will be the lowest dose possible.

**The elderly (over 65 years):**

If you are elderly, your doctor will tell you the correct dose to take. This will be the lowest dose possible.

**Taking this medicine**

If you have a sensitive stomach, take this medicine with or just after food. If taken shortly after eating, the onset of action of Abfen may be delayed.

- Empty the granules from one sachet into a small glass of water (about 125 ml).
- Make sure that you use all of the granules in the sachet.
- Stir the medicine until it stops bubbling and the granules have dissolved - this will make an orange flavoured, fizzy drink.
- If you use more than one sachet at one time, you should use more water. Use about 125 ml for each sachet of medicine.

**If you take more Abfen than you should**

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

taken. Take the medicine pack with you.

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 Abfen**

- If you forget a dose, take it as soon as you remember. However, if it is nearly time for your next dose, skip the missed dose.
- Do not take a double dose to make up for a forgotten dose.

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

#### **4. Possible side effects**

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

##### **Serious side effects**

**Stop taking this medicine and see your doctor straight away if you notice any of the following serious side effects - you may need urgent medical attention:**

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

- signs of bleeding from the stomach or gut such as passing blood in your faeces (stools/motions), passing black tarry stools or vomiting any blood or dark particles that look like coffee grounds
- Liver, kidney problems or difficulty urinating

Abfen, especially when taken at higher than recommended doses or for a prolonged period of time, can cause damage to your kidneys and affect them removing acids properly from your blood into the urine (renal tubular acidosis). It can also cause very low levels of potassium in your blood (see section 2). This is a very serious condition and will require immediate treatment. Signs and symptoms include muscle weakness and light-headedness.

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

- swelling of the face, tongue or throat (larynx) which can cause great difficulty in swallowing and breathing (angioedema)

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

- rapid heartbeat, severe fall in blood pressure or life threatening shock

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

- Reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms [exfoliative dermatitis, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis].
- severe infection with destruction (necrosis) of skin, subcutaneous tissue and muscle; this may occur in exceptional cases during chicken pox

##### ***Not known (we do not know how often these happen):***

- Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome)

- A red, scaly widespread rash with bumps under the skin and blisters accompanied by fever. The symptoms usually appear at the initiation of treatment (acute generalised exanthematous pustulosis). Stop using <Brufen> if you develop these symptoms and seek medical attention immediately. See also section 2.
- Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome

Stop taking this medicine and see your doctor straight away if you notice any of the side effects above.

**Stop taking this medicine and tell your doctor if you notice any of the following:**

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

- indigestion or heartburn
- abdominal (stomach) pains or other abnormal stomach symptoms

Stop taking this medicine and tell your doctor if you notice any of the side effects above.

**Other side effects**

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

- rash
- feeling dizzy or tired
- loss of appetite, diarrhoea, feeling sick, being sick, wind, constipation
- headache - if this happens while you are taking this medicine it is important not to take any other medicines for pain to help with this.

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

- feeling drowsy
- feeling anxious
- feeling a tingling sensation or ‘pins and needles’
- difficulty sleeping
- hives, itching
- skin becomes sensitive to light
- visual disturbances, hearing problems
- ringing in ears (tinnitus)
- sensation of feeling dizzy or spinning (vertigo)
- hepatitis, yellowing of your skin or eyes, reduced liver function
- reduced kidney function, inflammation of the kidneys, kidney failure
- sneezing, blocked, itchy or runny nose (rhinitis)
- stomach or gut ulcer, hole in the wall of the digestive tract
- inflammation of your stomach lining
- small bruises on your skin or inside your mouth, nose or ears
- difficulty breathing, wheezing or coughing, asthma or worsening of asthma
- changes in blood count - the first signs are: high temperature, sore throat, mouth ulcers, flu-like symptoms, feeling very tired, bleeding from the nose and the skin
- reduction in blood cells (anaemia)

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

- feeling depressed or confused
- fluid retention (oedema)
- a brain infection called ‘non-bacterial meningitis’
- loss of vision

- liver damage

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

- heart failure, heart attack, high blood pressure
- liver failure
- inflammation of the pancreas
- skin problems (which can also affect inside your mouth, nose or ears) such as ‘Stevens-Johnson syndrome’, ‘toxic epidermal necrolysis’ or ‘erythema multiforme’.

**Not known (we do not know how often these happen):**

- prolonged bleeding time
- worsening of ulcers in the large intestine (colitis) or Crohn’s Disease (bowel disease)
- burning feeling in the throat or mouth - this may happen briefly after taking this medicine.

**The following side effects have also been reported with other NSAIDs:**

- high blood pressure or heart failure
- worsening of ulcers in the large intestine and Crohn’s disease (bowel disease)
- a small 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 Yellow card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

**5. How to store Abfen**

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

Do not store above 25°C. Store in the original package in order to protect from light and moisture.

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

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 Abfen contains**

- The active substance is ibuprofen. Each sachet contains 600 mg of ibuprofen.
- The other ingredients are croscarmellose sodium, malic acid, microcrystalline cellulose, saccharin sodium, sucrose, povidone, orange flavour, sodium laurilsulfate, sodium hydrogen carbonate and sodium carbonate, anhydrous.

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

Abfen 600 mg Effervescent Granules are a white powder with an orange flavour.

Your medicine will be in a sachet.

After reconstitution, the suspension has a white, translucent appearance, free from foreign substances, with an orange odour.

Each pack contains 10, 20, 30, 40 or 50 sachets.

## **Marketing Authorisation Holder and Manufacturer**

*Marketing Authorisation Holder:*

Mylan Products Ltd, 20 Station Close, Potters Bar , Herts, EN6 1TL, UK

*Manufacturer:*

Abbvie S.r.l., S.R.148 Pontina km 52 snc, 04011 Campoverde di Aprilia (LT), Italy

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

United Kingdom	Abfen 600 mg Effervescent Granules
Estonia	Brufen
Hungary	Brufen 600 mg Pezsgőgranulátum
Ireland	Brufen 600 mg Effervescent Granules
Latvia	Brufen 600 mg putojošās granulas
Lithuania	Brufen 600 mg šnypščiosios granulės

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