

Package leaflet: Information for the user

PROVIN 100mg/5ml Oral Suspension Ibuprofen

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

Always use this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If your child gets any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if your child does not feel better or feels worse after 3 days or for infants aged 3 -5 months, after 24 hours.

What is in this leaflet

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

1 What Provin Oral Suspension is and what it is used for

Ibuprofen belongs to a group of medicines called non-steroidal anti-inflammatory painkillers (NSAIDs). This medicine is used for the relief of pain from teething and toothache, earache, backache, minor muscular pains, aches and sprains. It can also be used to bring down high temperature (also called fever) and relieve the symptoms of colds and flu.

This product is intended for use in children aged 3 months to 12 years.

2 What you need to know before you use Provin Oral Suspension

X Do not give your child this medicine:

- If s/he is allergic to ibuprofen or any of the ingredients of this medicine (listed in section 6).
- If s/he has had a **bad allergic reaction** (e.g. asthma, runny nose, swelling of face, tongue and throat, rash) after taking Ibuprofen, or any other ingredient (see section 6), **aspirin** or **non-steroidal anti-inflammatory (NSAIDs) painkillers**.
- If s/he weighs less than 5 kg.
- If s/he is taking any other anti-inflammatory painkillers (NSAIDs), for example **cyclooxygenase-2** inhibitors, or aspirin with a daily dose above 75 mg.
- If s/he has (or has had two or more episodes of) a **stomach ulcer, perforation or bleeding**.
- If s/he has **severe kidney, heart or liver failure**.
- If s/he has a history of gastrointestinal bleeding or perforation related to previous NSAID therapy.

If any of these apply, get advice from a doctor or pharmacist without using Provin.

! Warnings and Precautions

Talk to your doctor or pharmacist before using Provin

- If your child has or has previously had **high blood pressure, heart problems or a stroke** because there is a small increased risk of heart problems with Ibuprofen.
- If your child has any conditions which may put them at risk of **heart problems** e.g. suffers from **diabetes**, has **high cholesterol**.
- If your child has **asthma or allergic diseases of the lungs**.
- If your child has or has previously had **liver, kidney, heart or bowel problems or is dehydrated**
- If your child suffers from **lupus (SLE)** or a similar disease.
- If your child suffers from a **chronic inflammatory bowel disease** such as Crohn's disease or ulcerative colitis.
- If your child suffers from peptic ulceration.
- If your child suffers from coagulation defects.
- If your child suffers from fluid retention
- There is a small increase in the risk of heart failure, stroke and peptic ulceration when taking this medicine.
- During chicken pox (varicella) as it is advisable to avoid the use of ibuprofen.

Other medicines and Provin Oral Suspension

Provin 100mg/5ml Oral Suspension may affect or be affected by some other medicines. For example:

- low-dose **aspirin (up to 75 mg a day)**
- diuretics (drugs to **help you pass water** e.g. bendroflumethiazide)
- medicines that are anticoagulants (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)
- lithium (used to treat **mood disorders**)
- methotrexate (used to treat **arthritis, some types of cancer and psoriasis**)
- zidovudine (used to treat **HIV**)
- corticosteroids (a type of **anti-inflammatory** drugs, e.g. hydrocortisone)
- cardiac glycosides (drugs used in the treatment of **heart failure and arrhythmias (abnormal heart rhythm** e.g. digoxin).
- ciclosporin (used to **suppress the body's immune system e.g. following a transplant**).
- mifepristone
- quinolone antibiotics (used to treat a wide range of **infections** e.g. ciprofloxacin).
- SSRI antidepressants (e.g. fluoxetine).
- antiplatelet drugs (e.g. clopidogrel)
- tacrolimus (a **transplant** drug)
- any other Ibuprofen preparations or NSAID painkillers including those you can buy without a prescription.

If you are not sure about any of the medicines your child is taking, show the bottle or pack to your pharmacist.

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

If adults take this medicine

The above warnings and information apply and in addition the following:

- Speak to your doctor or pharmacist before using this product if you are elderly or are a smoker.
- Do not take ibuprofen with alcohol as it may increase the risk of stomach bleeding.
- 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 Provin 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.

Provin Oral Suspension with food and drink

There are no restrictions when taking this medicine with food and drink.

Pregnancy, breast-feeding and fertility

- Ibuprofen belongs to a group of medicines which may impair fertility in women. The effect is reversible on stopping the medicine. It is unlikely that Ibuprofen, used occasionally, will affect your chances of becoming pregnant, however, tell your doctor before taking this medicine if you have problems becoming pregnant.
- You should only take this product on a doctor’s advice during the first 6 months of pregnancy.
- Do NOT take Ibuprofen if you are in the last 3 months of pregnancy due to potential harm to the unborn child.

Driving and using machines

Taking this medicine does not affect your ability to drive or using machines.

Provin Oral Suspension contains sodium methylhydroxybenzoate, sodium propylhydroxybenzoate and maltitol:

- Sodium methylhydroxybenzoate (E219) and sodium propylhydroxybenzoate (E217) may cause allergic reactions which could possibly be delayed.
- This product contains maltitol. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.
- Maltitol may have a mild laxative effect. Calorific value 2.3 kcal/g maltitol. Each 5 ml of Provin contains 1 ml of maltitol liquid.

3 How to use Provin Oral Suspension

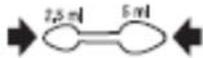
Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Check the information below to see how much medicine to use.

- Always **shake the bottle** thoroughly before use.

- Do not use more medicine than shown in the instructions below.
- Do not overfill the spoon.

There is a double ended measuring spoon in the pack, which is to be used to measure doses of 2.5 ml and 5 ml.



Babies under 3 months

Do not give to babies under 3 months. Consult your doctor.

Children from 3 months to 12 years

For Pain and Fever Relief:

Age

3 months - 6 months

- weighing over 5 kg

Dose

One 2.5 ml spoonful

3 times a day. Do not use for more than 24 hours

6 months - 1 year

One 2.5 ml spoonful

3 times a day

1 year - 2 years

One 2.5 ml spoonful

3 or 4 times a day

3 years - 7 years

One 5 ml spoonful

3 or 4 times a day

8 years - 12 years

Two 5 ml spoonfuls

3 or 4 times a day

- Doses should usually be given every 6 - 8 hours. Leave at least 4 hours between doses.
- Short term use only:
 - If symptoms persist or worsen or new symptoms occur, consult your doctor.
 - **DO NOT EXCEED THE STATED DOSE.**

Speak to your doctor

- For children aged 3-5 months medical advice should be sought if symptoms worsen or not later than 24 hours if symptoms persist
- If in children aged from 6 months, this medicinal product is required for longer than 3 days, or if symptoms worsen a doctor should be consulted.
- If you are not sure of your child's illness or it is accompanied by a rash, breathing difficulties, diarrhoea or excessive tiredness or lethargy, speak to your doctor straight away. Do not give Provin until you get medical advice.

If you use more Provin Oral Suspension than you should

If anyone has taken too much of this product, contact a doctor or your nearest Accident and Emergency Department (Casualty), taking this leaflet and pack with you.

If you forget to give Provin Oral Suspension

If you forget a dose, give the next dose when needed, provided that the last dose was taken at least 4 hours ago.

Do not take a double dose.

4 Possible side-effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The most common side-effect is irritation of the stomach which can cause problems (e.g. indigestion, heartburn) in some people.

If your child experiences any of the following, stop giving the medicine and seek immediate medical help:

- blood in the faeces (stools/motions)
- black tarry stools
- vomiting blood or dark particles that look like ground coffee
- unexplained wheezing, shortness of breath, skin rash (which may be severe and include blistering or peeling of the skin), itching or bruising, lightheadedness or racing heart, shock or fall in blood pressure or fluid retention e.g. swollen ankles or decreased levels of urine passed.
- stiff neck, headache, vomiting, fever and disorientation.
- severe hypersensitivity reactions such as swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing,
- peptic ulceration (peptic ulcer of the stomach).

If your child experiences any of the following, stop giving this medicine and tell your doctor:

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

- Headache, dizziness, weakness and/or sleepiness, unexplained stomach pain, indigestion, feeling sick and/or vomiting.

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

- Constipation or diarrhoea
- Skin rashes and itching
- Bleeding

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

- Severe sore throat with high fever, unexplained bruising, bleeding or tiredness or getting more infections (such as colds) than usual
- wind
- Kidney problems or kidney failure.
- Stroke, heart attack, heart failure or high blood pressure may occur with Ibuprofen but this is very unlikely at the doses given to children.
- Inflammation of the digestive tract and stomach, including Colitis and ulcerative stomatitis (ulcers of the stomach)
- Stomach ulcers, bleeding or perforated ulcers
- Inflammation of the pancreas
- Blurred or impaired vision

- Burning sensation or irritation of the mouth
- Feeling of restlessness including agitation, anxiety or nervousness
- Yellowing of the eyes and/or skin which maybe a sign or liver problems
- swelling of hands, ankles or feet (oedema)

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

- Inflammation of the digestive tract (Crohn’s disease)

The undesirable effects may be minimized by using the lowest effective dose for the shortest duration necessary to control symptoms.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRAs Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Provin Oral Suspension

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

Do not use this medicine after the expiry date which is stated on the bottle, label and carton.

Do not store above 25°C.

Do not throw away any medicines via wastewater or household waste. Ash 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 Provin Oral Suspension contains

The active substance is: Ibuprofen

The other ingredients are: Glycerol (E422), xanthan gum, maltitol (E965), polysorbate 80, saccharin sodium (E954), citric acid monohydrate, sodium methylhydroxybenzoate (E219), sodium propylhydroxybenzoate (E217), purified water. The flavouring is strawberry.

What Provin Oral Suspension looks like and contents of the pack

Provin 100 mg/5 ml Oral Suspension is a whitish liquid, available in 100ml and 150ml bottles. It contains 100 mg of the active ingredient Ibuprofen in every 5 ml of medicine.

Marketing Authorisation Holder and Manufacturer

The Product Authorisation holder is McNeil Healthcare (Ireland) Ltd., Airton Road, Tallaght, Dublin 24, Ireland.

The manufacturer is Pinewood Laboratories Ltd., Ballymacarbry, Clonmel, Co. Tipperary, Ireland.

This leaflet was last revised July 2017.