Package leaflet: Information for the user

Tefin 75mg Suppositories
ibuprofen
FOR RECTAL ADMINISTRATION ONLY

FOR INFANTS
Age 8 months up to 3 years

Contains Ibuprofen

Read all of this leaflet carefully before you start taking Tefin because it contains important information for you and your child
- Always take this medicine exactly as described in this leaflet or as your pharmacist or doctor has told you.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist or doctor if you need more information or advice.
- If you get any side effects, talk to your pharmacist or doctor. This includes any possible side effects not listed in this leaflet (See section 4).
- If Tefin is required for three days or if symptoms worsen, you should consult a doctor.

In this leaflet:

1. What Tefin is and what it is used for

Tefin contains ibuprofen which is a non-steroidal anti-inflammatory drug (NSAID). NSAIDs are medicines which have pain-relieving (analgesic) effects and also have the effect of reducing inflammation (anti-inflammatory), swelling and temperature. They are also used to soothe away pain from teething, toothache, earache, headache, cold and flu symptoms, sore throats, strains and sprains.

Tefin is used in children for the symptomatic treatment of :
- mild to moderate pain,
- fever.

2. What you need to know before you give Tefin to your child

Do not give Tefin to your child if:

- your child is allergic (hypersensitive) to ibuprofen or any of the other ingredients of Tefin (see section 6);
- in the past your child **developed asthmatic attacks**, swelling of the nasal mucosa or skin reactions after taking aspirin (acetylsalicylic acid /ASA), ibuprofen or other nonsteroidal anti-inflammatory drugs;
- your child has a **blood count disorder**;
- your child has a **history of bleeding from the stomach or intestine** (e.g. gastric or intestinal perforation) caused by treatment with nonsteroidal anti-inflammatory drugs;
- your child has **bleeding from the brain vessels** (cerebrovascular haemorrhage) or other active bleeding;
- your child is suffering from or has suffered **from active ulcers of the stomach or duodenum,** with at least two clearly identified episodes of proven ulceration or bleeding;

- your child has **serious liver or kidney problems**;
- your child has **congestive heart failure** (insufficiency of the heart);
- your child is **younger than eight months or weighs less than 7.5 kilograms**, since this product is not suited for such patients due to its active substance
- you notice deterioration (allergic reactions, gastrointestinal bleeding).

Warnings and precautions
Talk to your doctor before use if your child has:
- **kidney** or **liver problems**;
- **stomach or intestinal disorders** (such as ulcerative colitis or Crohn's disease);
- Any problem with the **rectum** or **anal area (back passage)**
- **diabetes**;
- any **problems with blood clotting** or **excessive bruising**;
- recently had **major surgery**;
- **allergies** (e. g. skin reactions to other medicines, asthma, hay fever);
- **asthma**, chronic swelling of the mucous membranes or chronic obstructive airways diseases;
- **congenital disturbance of porphyrin metabolism** (e. g. acute intermittent porphyria);
- certain **diseases of the immune system** (systemic lupus erythematosus and mixed collagen disease) or **serious skin disease**.
- during **chicken pox** (varicella) it is advisable to avoid the use of Tefin.
- an infection - please see heading "Infections" below.

If your child suffers from any of the above conditions, close medical supervision is necessary.

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.

Skin reactions
Serious skin reactions have been reported in association with Ibuprofen treatment. You should stop taking Tefin 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**.**

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

You should discuss treatment with your doctor or pharmacist before taking Tefin if your child:

- has heart problems including heart failure, angina (chest pain), or if your child has had a heart attack, bypass surgery, peripheral artery disease (poor circulation in the legs or feet due to narrow or blocked arteries), or any kind of stroke (including 'mini-stroke' or transient ischaemic attack "TIA").

- has high blood pressure, diabetes, high cholesterol, has a family history of heart disease or stroke, or if your child is a smoker.

If your child is dehydrated, there is a risk that Tefin will cause kidney damage.

In case of long-term treatment with Tefin, liver and kidney function should be monitored and blood counts should be carried out on a regular basis.

If Tefin is used before surgery, the doctor or dentist should be consulted or informed.

Other medicines and Tefin
Tell your doctor or pharmacist if your child is taking, or if your child has recently taken any other medicines, including medicines obtained without a prescription.

Do not take or give Tefin in combination with:
- other NSAIDs (nonsteroidal anti-inflammatory drugs) such as aspirin, including selective Cox-2 inhibitors (cyclooxygenase-2 inhibitors).

Consult your doctor before use if your child is taking any of the following medicines:
- **digoxin** (used to increase the force of the heart);
- **phenytoin** (used to treat convulsions or epilepsy);
- **lithium** (used for the treatment of mental disorders);
- medicines that are anti-coagulants (i.e. thin blood/prevent clotting e.g. **acetylsalicylic acid/aspirin, warfarin, ticlopidine, heparin**);
- some medicines to treat high blood pressure (ACE-inhibitors such as **captopril**, betareceptor blocking medicines such as **atenolol,** angiotensin II antagonists such as **losartan**);
- **diuretics** (to help pass water) e.g. furosemide
- other analgesics (painkillers);
- glucocorticoids (such as **hydrocortisone or prednisolone);**
- **methotrexate** (used to treat autoimmune diseases);
- **ciclosporin** or **tacrolimus** (used to prevent transplant rejection and for the treatment of rheumatism);
- **probenecid** or **sulphinpyrazone** (used for the treatment of gout);
- **sulphonylureas** (used to lower blood sugar levels in diabetes);
- **zidovudine** (used to treat HIV).
- **aminoglycosides** (antibiotics for infections)
- **quinolones** (antibiotics for infections).
- antiplatelet drugs such as **dipyridamole** or **clopidogrel**
- **SSRI** anti-depressant drugs.
- **Mifepristone** now or in the past 12 days

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

Tefin with food and drink and alcohol
Alcohol should be avoided during treatment with Tefin. Alcohol may increase the side-effects, especially reactions affecting the gastrointestinal tract and the central nervous system.

Pregnancy and breast-feeding and fertility

Pregnancy
Tell your doctor if you become pregnant during treatment with Tefin. In the first six months of pregnancy, Tefin should only be used after consultation with your doctor. Tefin must not be used in the last three months of pregnancy because it carries an increased risk of complications affecting both the mother and the child.

Tefin is among a group of medicines inhibiting the synthesis of prostaglandins (nonsteroidal anti-inflammatory drugs) which may make it difficult to become pregnant. This effect is transient and disappears after stopping treatment with Tefin.

Breast-feeding
Breast-feeding need not usually be stopped, as long as the medicinal product is given for a short period of time. However, early discontinuation of breast-feeding should be considered, if large doses are given for extended periods of time.

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

Driving and using machines

As Tefin given in high doses may cause central nervous system-related side-effects such as fatigue and dizziness, the patient's reaction can be modified and his ability to drive a car or operate machinery can be impaired. This is especially true in combination with alcohol. You may be unable to react properly and rapidly to certain situations happening quickly and unexpectedly. In such circumstances, you should not drive a car, use tools or operate machinery.

3. How to use Tefin

Always use Tefin exactly in accordance with the instructions in this leaflet. You should check with your doctor or pharmacist if you are not sure.

- If Tefin is required for three days or if symptoms worsen, you should consult a doctor.
- Tefin should always be used in accordance with the doses specified in this leaflet.
- If you are unsure of your child's illness or if it is accompanied by a rash, breathing difficulties, diarrhoea or excessive tiredness, speak to your doctor straight away.
- Tefin must not be taken by mouth

If your child needs to empty his/her bowels, make sure it is done before you insert a suppository. Remove the suppository from the foil. The suppositories should be put deep into the rectum (back passage). They may be warmed up in the hands or dipped for a short time into warm water to improve their sliding properties. Wash your hands before and after using Tefin.

Unless otherwise prescribed by your doctor, the usual doses are:

Age	**Body weight**	**Single dose**	**Maximum number of suppositories in 24 hours (maximum dose of ibuprofen in 24 hours)**
8 to 12 months	7.5 to 10 kg	1 suppository (75 mg)	3 suppositories (225 mg daily)
12 months to 3 years	10 to 15 kg	1 suppository (75 mg)	4 suppositories (300 mg daily)

If your child has used a single dose, you should wait for at least 6 hours before using the medicinal product again.

Do not exceed the stated dose. 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).

Please tell your doctor or pharmacist if you feel the effect of Tefin is too strong or too weak.

If you give too much Tefin to your child

If you have given your child more Tefin than you should, or if Tefin has been taken by accident, always contact a doctor or the nearest 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 give Tefin to your child

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

The evaluation of side effects is based on the following incidence rates:

Very common:	More than 1 out of 10 treated patients.
Common:	Fewer than 1 out of 10, but more than 1 out of 100 treated patients.
Uncommon:	Fewer than 1 out of 100, but more than 1 out of 1000 treated patients.
Rare:	Fewer than 1 out of 1000, but more than 1 out of 10000 treated patients.
Very rare:	Less than 1 out of 10000 treated patients, or unknown
Not known:	Incidence cannot be estimated from the available data.

Tell your doctor immediately and stop using Tefin if your child suffers from:
- severe hypersensitivity reactions, such as swelling of the face, tongue and larynx (throat) with constriction of the airways, respiratory distress (breathing difficulty), wheezing, worsening of asthma, rapid heart rate and fall in blood pressure;
- severe pain in the upper abdomen (stomach), vomiting of blood or dark particles that look like coffee grounds, blood-stained stool and/or black coloration of the stool;
- skin reactions including rashes (erythema or redness) and formation of blisters (exfoliative dermatitis, Stevens-Johnson syndrome and toxic epidermal necrolysis/Lyell`s syndrome);
- disturbances of the blood count (anaemia or low blood count, leucopenia or low white cells (infection fighting cells), thrombocytopenia (low platelet count causing difficulty in clotting), pancytopenia (low count in all blood cells), agranulocytosis (no white cells / infection fighting cells)). The first signs may be: fever, sore throat, inflammation or ulcers in the mouth, flu-like symptoms, weariness or listlessness, skin bruising, nosebleeds or other bleeding.

These may be serious life threatening conditions which may occur very rarely.

Tell your doctor immediately if your child experiences:
- recurrence or aggravation of signs of an infection (e. g. erythema (redness), swelling, overheating, pain, fever) during treatment with Tefin;
- reduced amount of urine, accumulation of water in the body (oedema) which may show as ankle swelling.

These may be serious life threatening conditions which may occur very rarely.

Consult your doctor if your child experiences any of the following side effects:

Common:
- heartburn, abdominal (stomach) pain, nausea, vomiting, flatulence, diarrhoea or constipation;
- blood loss from the gastrointestinal tract (stomach and bowel), giving rise to anaemia (low blood count) in exceptional cases;

- local irritation at the administration site, secretion of bloodstained mucus and painful bowel movement.

Uncommon:
- headache, dizziness, sleeplessness, agitation, irritability or fatigue;
- vision disorders;
- ulcers of the stomach and the duodenum (peptic ulcers), sometimes accompanied by bleeding and perforation, inflammation of the oral mucosa with ulcers (ulcerative stomatitis / swelling and ulcers in the mouth), aggravation of ulcerative colitis or Crohn's disease;
- inflammation of the lining of the stomach (gastritis);
- allergic reactions with rash and itching as well as asthmatic attacks (possibly with fall in blood-pressure).

Rare:
- ringing in the ears (tinnitus).

Very rare:
- fast heart rate, cardiac insufficiency (heart failure), heart attack or stroke;
- disturbances of the blood count (anaemia or low blood count, leucopenia or low white cells (infection fighting cells), thrombocytopenia (low platelet count causing difficulty in clotting), pancytopenia (low count in all blood cells), agranulocytosis (no white cells / infection fighting cells)).
- inflammation of the oesophagus (oesophagitis) and the pancreas (pancreatitis);
- abnormally large amounts of fluid in the tissues (oedema), especially in patients with high blood pressure or impaired kidney function; nephrotic syndrome (accumulation of water in the body (oedema) and increased excretion of proteins in the urine); inflammatory disease of the kidneys, which may be accompanied by impaired kidney function;
- high blood pressure (arterial hypertension);
- kidney tissue damage and elevated uric acid concentrations in the blood;
- reduced amount of urine, accumulation of water in the body (oedema) and malaise may be a manifestation of kidney disease including kidney failure;
- loss of hair (alopecia);
- worsening of infections (e.g. development of necrotising fasciitis) after use of ibuprofen (the medicine in Tefin) has been reported. This reaction is related to the way that non-steroidal anti-inflammatory drugs (like Tefin) work by reducing inflammation;
- signs of inflammation of the lining of the brain (aseptic meningitis) such as severe headache, nausea, vomiting, fever, neck stiffness or disorientation have been reported. Patients suffering from diseases of the immune system (systemic lupus erythematosus and mixed collagen disease) seem to be at an increased risk;
- impaired liver function, liver damage, especially in patients on long-term treatment, hepatic failure (liver failure), acute hepatitis (liver inflammation), yellow jaundice;
- psychotic reactions or depression.

Not known:
- 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 Tefin if you develop these symptoms and seek medical attention immediately. See also section 2.
- skin becomes sensitive to light

Drug reaction with eosinophilia and systemic symptoms (DRESS syndrome):

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 cell).

In exceptional cases, varicella infection (the virus that causes chicken pox) may be accompanied by severe skin infections and complications affecting the soft tissues (see above).

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 HPRA Pharmacovigilance, Earlsfort Terrace, Dublin, D02 XP77, Ireland; 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 Tefin

Keep out of the sight and reach of children.

Do not store above 25 °C.

Do not use Tefin after the expiry date which is stated on the blister and the carton after EXP. The expiry date refers to the last day of the month.

Do not use Tefin if you notice any change in colour, shape or texture of the suppository (it should be a white, odourless, torpedo-shaped suppository).

Do not throw away any medicines 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 further information

What Tefin contains

The active substance is ibuprofen, one suppository contains 75 mg of ibuprofen.
The other ingredient is hard fat.

What Tefin looks like and contents of the pack

White, odourless, torpedo-shaped suppositories.

Tefin is available in packs containing 10 suppositories and hospital-only 100 pack sizes (10 x 10).

Not all pack sizes may be marketed.

Marketing authorisation holder and manufacturer

Manufacturer
bene-Arzneimittel GmbH
Herterichstrasse 1
D-81479 Munich
Germany

Marketing authorisation holder
Clonmel Healthcare Ltd.,
Waterford Road,
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