Tefin 150mg Suppositories

Ibuprofen

INFORMATION FOR THE USER

FOR RECTAL ADMINISTRATION ONLY

For children age 3 years up to 9 years
Contains ibuprofen

Read all of this leaflet carefully because it contains important information for you and your child.
This medicine is available without prescription. However, you still need to use Tefin carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If Tefin is required for three days or if symptoms worsen, you should consult a doctor.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your child's doctor or a pharmacist.

In this leaflet:

1. What Tefin is and what it is used for

Tefin contains ibuprofen. This belongs to a group of medicines known as non-steroidal anti-inflammatory drugs (NSAIDs). 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. Before you give Tefin to your child

Do not give Tefin to your child if:
- you or your child is allergic (hypersensitive) to ibuprofen or any of the other ingredients of Tefin;
- in the past you or your child **developed asthmatic attacks**, swelling of the nasal mucosa or skin reactions after taking aspirin (acetylsalicylic acid /ASA) 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 bleedings;
- your child is suffering from or has suffered **from active ulcers of the stomach or duodenum**, with at least two clearly identified episodes of proved 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 3 years or weighs less than 15 kilograms**, since this product is not suited for such patients due to its active substance
- you notice deterioration (allergic reactions, gastrointestinal bleeding).

Take special care with Tefin
Consult your doctor before use if your child has:
- **kidney or liver problems**;
- **stomach or intestinal disorders** (such as ulcerative colitis or Crohn's disease);
- **heart problems** or is at risk of heart problems;
- ever had **high blood pressure and/or heart failure**;
- **diabetes**;
- any **problems with blood clotting**;
- recently had **major surgery**;
- or you have **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);
- a certain **disease of the immune system** (systemic lupus erythematosus and mixed collagen disease).

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

Medicinal products like Tefin suppositories might be accompanied by a slightly increased risk of heart attacks (myocardial infarction) or stroke. Any risk is increased by the administration of large doses and by prolonged treatment. The recommended dose and duration of treatment (not more than three days) should therefore not be exceeded.

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 carried out on a regular basis..

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

Using other medicines
Please 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:
- **digoxin** (a medicinal product increasing the force of the heart);
- **phenytoin** (a medicinal product to treat convulsions);
- **lithium** (a medicinal product for the treatment of mental disorders);
- medicines that are anti-coagulants (against clotting) (e.g. acetylsalicylic acid/aspirin, warfarin, ticlopidin);
- some medicines to treat high blood pressure (**ACE-inhibitors**, e.g. **captopril**, **betareceptor blocking medicines**, **angiotensin II antagonists**);
- antiphyertensive drugs (**diuretics and antihypertensives**);
- a**nalgesics**;
- glucocorticoids (such as **hydrocortisone or prednisolone**);
- **methotrexate** (used to treat autoimmune diseases);
- **ciclosporin** or **tacrolimus** (medicinal products used to prevent transplant rejection and for the treatment of rheumatism);
- medicinal products containing **probenecid** or **sulphinpyrazone** (used for the treatment of gout);
- **sulphonylureas** (used to lower blood sugar levels);
- **zidovudine** (used to treat HIV).

Using Tefin with food and drink
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
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. The medicinal product 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 for a 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 give Tefin to your child

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 feel the medicinal product does not give sufficient relief to your child, consult with your doctor who will advise if you need to increase the dose.

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

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)
3 to 6 years	15 to 20kg	1 suppository (150mg)	3 suppositories (450mg daily)
6 to 9 years	20 to 29kg	1 suppository (150mg)	4 suppositories (600mg daily)

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

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
Please inform your doctor if you suspect an overdose of Tefin, even in case of a temporary relief of your child's symptoms. Depending on the severity of poisoning, your doctor will decide what measures should be taken.

Overdosing may lead to central nervous system disorders like headache, dizziness, somnolence (sleepiness) and unconsciousness (children can get seizures) and abdominal (stomach) pain, nausea and vomiting. Furthermore gastrointestinal (stomach and bowel) bleeding and dysfunction of liver and kidney are possible.

Some patients may develop hypotension (low blood pressure), respiratory distress (respiratory depression or breathing difficulties) and bluish red discoloration of the skin and the mucous membranes (cyanosis).
There is no specific antidote.

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, Tefin can cause side effects. It should be kept in mind that most of the following side effects are dose-related and vary considerably among individuals.

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

Very common:	More than 1 out of 10 treated patients.
Common:	Fewer than1 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 1.000 treated patients.
Rare:	Fewer than 1 out of 1000, but more than 1 out of 10.000 treated patients.
Very rare:	Less than 1 out of 10.000 treated patients, or unknown
Unknown:	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), rapid heart rates and fall in blood pressure;
- severe pain in the upper abdomen (stomach), vomiting of blood, 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 nekrolysis/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, nasal bleeding and skin 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 excretion of urine, accumulation of water in the body (oedema).

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:
<u>Common</u>:
- 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.

<u>Uncommon</u>:
- 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).

<u>Rare</u>:
- ringing in the ears (tinnitus).

<u>Very rare</u>:
- fast heart rate, cardiac insufficiency (heart failure) or heart attack;
- 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 functions;
nephrotic syndrome (accumulation of water in the body (oedema) and increased excretion of proteins in the urine); inflammatory disease of the kidneys (interstitial nephritis), which may be accompanied by impaired kidney function;
- high blood pressure (arterial hypertension);
- renal tissue damage (papillary necrosis) and elevated uric acid concentrations in the blood;
- reduced excretion of urine, accumulation of water in the body (oedema) and malaise may be a manifestation of kidney disease including kidney failure;
- severe skin reactions such as rash with redness of the skin and formation of blisters (e. g. Stevens-Johnson syndrome, toxic epidermal necrolysis/Lyell`s syndrome), loss of hair (alopecia);
- worsening of infections (e. g. development of a necrotizing fasciitis) having a temporal association with the use of Tefin has been reported. This reaction is related to the mode of action of medicinal products reducing inflammation (nonsteroidal anti-inflammatory drugs, like Tefin);
- 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);
- psychotic reactions or depression.

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, 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 Tefin

Keep out of the reach and sight 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).

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. Further information

What Tefin contains
- The active substance is ibuprofen, one suppository contains 150 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

Marketing authorisation holder
Carysfort Healthcare Limited,
93 Carysfort Park,
Blackrock,
Co. Dublin,
Ireland.
01 2882332

PA 1684/1/2

This leaflet was last revised in:
July 2014

Carysfort Healthcare