

## PATIENT COUNSELLING INFORMATION

### Ibuprofen & Paracetamol Suspension

#### Flexon<sup>®</sup> Suspension

##### Read the entire leaflet carefully before you start taking this medicine:

- If you have any further questions, ask your doctor.
- This medicine has been prescribed for you only. Do not pass it on to others, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet.

#### 1. What is Flexon<sup>®</sup> Suspension and what is it used for?

Flexon<sup>®</sup> Suspension is a combination of Ibuprofen and Paracetamol. Paracetamol is a non-salicylate antipyretic and non-opioid analgesic agent. Ibuprofen is a propionic acid derivative Non-steroidal anti-inflammatory drug (NSAID), reduces inflammatory pain, swelling and fever.

#### 2. What you need to know before you take Flexon<sup>®</sup> Suspension?

Before taking Flexon<sup>®</sup> Suspension, tell your doctor,

- If your child is taking any other Paracetamol or NSAIDs containing products, other flu, cold, cough or decongestant products.
- If your child is allergic (hypersensitive) to Paracetamol or Ibuprofen, or any of the other ingredients.
- If your child has had an allergic reaction or wheezing after taking aspirin or other non-steroidal anti-inflammatory painkillers.
- If your child has ever had a stomach ulcer or a history of bleeding into, or perforation of, the intestine especially after previous NSAID treatment.
- If your child has ever had severe kidney, heart or liver problems.
- If your child is less than 3 months old.

If you are taking, or have recently taken, or might take any other medicines, even those obtained without a prescription, but especially medicines which:

- are to treat 'flu' or a cold, containing Paracetamol and/or Ibuprofen. Do NOT give with other Paracetamol products.
- control nausea and vomiting (e.g. domperidone or metoclopramide).
- reduce levels of cholesterol and other fats in the blood (e.g. colestyramine).
- treat epilepsy (e.g. anti-convulsants).
- are anticoagulants (i.e. thin blood/prevent clotting e.g. aspirin/acetylsalicylic acid, warfarin, ticlopidine).

- Methotrexate (used to treat rheumatoid arthritis, psoriasis and some cancers).
- Zidovudine (used to treat HIV).
- Corticosteroids (anti-inflammatory drugs, such as Hydrocortisone).
- Cardiac glycosides (drugs used in the treatment of heart problems, such as Digoxin).
- Ciclosporin or Tacrolimus (used to suppress the body's immune system).
- Quinolone antibiotics (used to treat a wide range of infections e.g. Ciprofloxacin).

### 3. How to take Flexon<sup>®</sup> Suspension?

Always take Flexon<sup>®</sup> Suspension exactly as your doctor has told you. If you are not sure, check with your doctor. Take Flexon<sup>®</sup> Suspension every day for as long as your doctor prescribes it.

Shake the bottle well before measuring the dose.

#### **If you take more Flexon<sup>®</sup> Suspension than you should**

It is important to keep to the dose as prescribed by your doctor. If you have taken more Flexon<sup>®</sup> Suspension than you should and if you are concerned about an overdose you should consult your doctor, if possible you should take the medicine pack with you.

#### **If you forget to take Flexon<sup>®</sup> Suspension**

If you forget to take a dose, take it as soon as you remember unless it is nearly time for your next dose. Take the next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

#### **If you stop taking Flexon<sup>®</sup> Suspension**

If you stop taking Flexon<sup>®</sup> Suspension, your symptoms may return. Tell your doctor before stopping Flexon<sup>®</sup> Suspension.

### 4. What are the possible side effects of Flexon<sup>®</sup> Suspension?

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

- You should STOP giving this medicine and seek advice from your doctor if your child experiences a very rare allergic reaction, including skin rashes, increased sensitivity to light, swelling of the face and tongue, or throat, difficulty swallowing, unexplained wheezing, shortness of breath which may be accompanied by skin rash (which may be severe and include blistering or peeling of the skin) or hives, fever or shock. Skin and mucous membrane reactions may also occur.

Tell your doctor as soon as possible if you notice any of these:

- Becoming unusually tired, unexpected bruising or bleeding and getting more infections (such as colds) than usual.
- Passing blood in their faeces (stools/motions).
- Passing black tarry stools.
- Vomiting blood or dark particles that look like ground coffee.
- Lightheadedness, racing of the heart or fluid retention e.g. swollen ankles, not passing enough urine.
- Stiff neck, headache, nausea, vomiting, severe sore throat with high fever and disorientation.
- Skin starts to turn red or they develop a varied skin reaction or their skin starts to blister or peel, this is very rare.
- Unexplained stomach pain, indigestion, heartburn, feeling sick.
- Yellowing of the eyes and/or skin.

**Other unusual effects may include:**

Uncommon:

- Headache.

Rare:

- Ibuprofen may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke. Any risk is more likely with high doses and prolonged treatment.
- Flatulence, diarrhoea or constipation.

Very Rare:

- Occasionally hypersensitivity reactions may occur which can cause skin rashes.
- Liver and kidney problems may occur with Ibuprofen.
- Crohn's disease or ulcerative colitis or other stomach problems may be exacerbated.

Unknown:

- 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).
- 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).

Long term use: people who use medicines containing Paracetamol every day for a long time (several months or more) could get certain side effects, including liver and kidney damage. People taking Paracetamol in the usual way for shorter periods have not had these problems.

## 5. How to store Flexon<sup>®</sup> Suspension?

Do not take this medicine after the expiry date shown on the pack. The expiry date refers to the last day of that month.

**Store in a cool, dark place. Protect from light.**

Shake well before use.

Keep out of reach of children.

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*For further information please write to :*



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