

## Package leaflet: Information for the user

### Ibuprofen/Phenylephrine Clonmel 400 mg/10 mg Film-coated Tablets

Ibuprofen/Phenylephrine hydrochloride

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

#### 1. What Ibuprofen/Phenylephrine Clonmel is and what it is used for

Ibuprofen/Phenylephrine Clonmel contains ibuprofen and phenylephrine hydrochloride, which are effective in relieving the symptoms associated with colds and flu, including relief of mild to moderate pain, nasal congestion (blocked nose) and lowering of temperature.

Ibuprofen belongs to a group of medicines known as non-steroidal anti-inflammatory drugs (NSAIDs) and is effective against aches and pains (including headache), swelling and can also reduce a fever. Phenylephrine hydrochloride (nasal decongestant) reduces swelling in the passages of the nose, relieving nasal congestion and reducing the pressure which may cause a headache.

Ibuprofen/Phenylephrine Clonmel is used to treat adults and children over 12 years.

#### 2. What you need to know before you take Ibuprofen/Phenylephrine Clonmel

##### **DO NOT take this medicine if you:**

- are allergic to ibuprofen, phenylephrine hydrochloride or any of the other ingredients of this medicine (listed in section 6), or to acetylsalicylic acid (aspirin) or other painkillers
- have ever had a stomach ulcer, perforation or bleeding
- have had a worsening of asthma, skin rash, itchy runny nose or facial swelling when previously taking ibuprofen, acetylsalicylic acid (aspirin) or similar medicines
- have had gastrointestinal bleeding or perforation when previously taking NSAIDs (Non-Steroidal Anti-Inflammatory Drugs)
- are taking other NSAID painkillers
- are taking more than 75 mg of acetylsalicylic acid (aspirin) a day. If you are on low-dose acetylsalicylic acid (up to 75 mg daily) talk to your doctor or pharmacist before you take this medicine.
- have severe liver or kidney problems
- have heart problems, high blood pressure or blood coagulation disorder
- have breathing difficulties
- have an overactive thyroid
- are taking or have taken within the last 14 days a medicine called monoamine oxidase inhibitor (usually used to treat depression)
- are in the last 3 months of pregnancy (**please see also section 2 “Pregnancy, breast-feeding and fertility”**)

- are under 12 years old

### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Ibuprofen/Phenylephrine Clonmel if you:

- have or have had asthma
- have kidney, heart, liver or bowel problems
- have high cholesterol or previously have had a heart attack or stroke
- have a history of gastrointestinal disease (such as ulcerative colitis or Crohn's disease)
- have Systemic Lupus Erythematosus (a condition of the immune system causing joint pain, skin changes or other organ disorders)
- are a smoker
- are in the first 6 months of pregnancy
- have diabetes
- have glaucoma
- have an enlarged prostate
- have a blood vessel disease such as Raynaud's phenomenon
- have an infection - please see heading "Infections" below

**Infections:** Ibuprofen/Phenylephrine Clonmel may hide signs of infections such as fever and pain. It is therefore possible that Ibuprofen/Phenylephrine Clonmel 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.

**Skin reactions:** Serious skin reactions have been reported in association with <product name> treatment. You should stop taking <product name> 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.

Anti-inflammatory/pain-killer medicines like ibuprofen may be associated with a small increased risk of heart attack (myocardial infarction) 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 Ibuprofen/Phenylephrine Clonmel 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

### **Children and adolescents**

There is a risk of renal impairment in dehydrated adolescents.

### **Other medicines and Ibuprofen/Phenylephrine Clonmel**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

To reduce the risk of side effects, do not take this medicine with other NSAID containing products (e.g. acetylsalicylic acid, ibuprofen). If you are on low-dose acetylsalicylic acid (aspirin) (up to 75 mg daily) talk to your doctor or pharmacist before you take this medicine.

Ibuprofen/Phenylephrine Clonmel may affect or be affected by some other medicine. For example:

Avoid taking this medicine with medicines

- used for the treatment of asthma and various inflammatory conditions (corticosteroid tablets, e.g. prednisolone, beclomethasone)

- to treat certain bacterial infections (quinolone antibiotics, e.g. ciprofloxacin, norfloxacin, levofloxacin)
- that are anti-coagulants (i.e. thin your blood/prevent clotting e.g. acetylsalicylic acid (aspirin), warfarin, ticlopidine)
- to stimulate your heart (e.g. glycosides including digoxin) or that reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol medicines, angiotensin-II receptor antagonists such as losartan)
- to help you pass water (diuretics)
- for the temporary suppression of your immune system (e.g. methotrexate, ciclosporin, tacrolimus)
- for mania or depression (e.g. lithium, SSRIs, Monoamine Oxidase Inhibitors, amitriptyline)
- for pregnancy termination (e.g. mifepristone)
- for HIV treatment (e.g. zidovudine)
- containing other sympathomimetic agents such as decongestants (e.g. pseudoephedrine)

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

### **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.

Tell your doctor if you become pregnant whilst taking Ibuprofen/Phenylephrine Clonmel. **DO NOT take this medicine in the last 3 months of pregnancy. DO NOT use this medicine in the first 6 months of pregnancy unless the doctor advises otherwise.**

**Talk to your doctor or pharmacist BEFORE taking this medicine if you are breast-feeding.**

Ibuprofen may make it more difficult to become pregnant. You should inform your doctor if you are planning to become pregnant or if you have problems to become pregnant.

### **Ibuprofen/Phenylephrine Clonmel contains sodium**

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

## **3. How to take Ibuprofen/Phenylephrine Clonmel**

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

### **Method of administration**

Tablets must be swallowed whole with water.

It is important to drink plenty of fluids when suffering from colds and flu.

### **Dosage**

#### **Adults, the elderly and children over 12 years:**

Take one tablet every 8 hours. Leave at least 4 hours between doses and do not exceed 3 tablets in any 24 hour period.

### **Duration of treatment**

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).

**Do not take Ibuprofen/Phenylephrine Clonmel for longer than 10 days.** If you do not feel better or get worse, talk to your doctor. He will tell you if it is safe to carry on taking this medicine.

Length of treatment is guided by the nature and severity of disease and should be decided by the treating doctor.

**Do not give to children under 12 years.**

**If you take more Ibuprofen/Phenylephrine Clonmel than you should**

If you have taken more Ibuprofen/Phenylephrine Clonmel 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.

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.

You may experience muscle weakness, tingling feelings such as “pins and needles”, and feel your heartbeat (due to raised levels of potassium in the blood which can be detected by blood tests). You should seek immediate medical advice, even if you feel well.

**If you forget to take Ibuprofen/Phenylephrine Clonmel**

Refer to the directions above on how to take this medicine and do not take more than is advised. **DO NOT take a double dose to make up for forgotten tablets.**

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.

Side effects may be minimized by taking the lowest dose for the shortest time necessary to relieve the symptoms. You may suffer one of the known side effects of NSAIDs (see below).

If you get any of the following at any time during treatment **STOP TAKING this medicine and seek immediate medical help:**

- **signs of intestinal bleeding** such as:
  - bright red faeces (stools/motions), black tarry stools
  - vomiting blood or dark particles that look like coffee grounds
- **signs of serious allergic reaction** such as:
  - difficulties in breathing or unexplained wheezing
  - dizziness or faster heartbeat
  - severe forms of skin reactions such as itchiness, skin rash with redness, peeling, flaking or blistering (e.g. Steven-Johnson syndrome)
  - swelling of your face, tongue or throat
  - 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) (not known: frequency cannot be estimated from the available data). Stop using Ibuprofen/Phenylephrine Clonmel if you develop these symptoms and seek medical attention immediately. See also section 2.
- **signs of kidney problems** such as:
  - passing less or more urine
  - cloudy urine or blood in urine
  - pain in the back and/or swelling (particularly in the legs)
- **signs of aseptic meningitis** such as:
  - neck stiffness

- headache
- feeling sick, being sick
- fever or disorientation. Patients with autoimmune disorders (Systemic Lupus Erythematosus, mixed connective-tissue disease) may be more likely to be affected.
- **signs of blood disorder** resulting in unexplained or unusual bruising or bleeding, fever, sore throat, mouth ulcers, flu-like symptoms and severe exhaustion
- **signs of liver problems** such as:
  - stomach pain, nausea,
  - jaundice (yellowing of the skin and the whites of the eyes) or passing dark brown urine.

**STOP TAKING this medicine and tell your doctor if you experience the following uncommon side effects which may affect up to 1 in 100 people:**

- indigestion, heartburn or feeling sick
- pains in your stomach (abdomen) or other abnormal stomach problems

**TELL YOUR DOCTOR if you have any of the following side effects, they become worse or you notice any effects not listed:**

**Uncommon side effects** which may affect up to 1 in 100 people:

- allergic reactions, such as skin rashes (urticaria), itching, peeling
- headaches, dizziness, tinnitus (ringing in the ears)

**Rare side effects** which may affect up to 1 in 1,000 people:

- flatulence (wind), diarrhoea, constipation and vomiting

**Very rare side effects** which may affect up to 1 in 10,000 people:

- drop in blood pressure or irregular heart beat

**Side effects** for which the frequency cannot be estimated from the available data:

- worsening of asthma or bronchospasm
- swelling (oedema), high blood pressure, heart failure or attack
- worsening of colitis and Crohn's disease
- difficulties in passing urine (in men only)

Medicines such as Ibuprofen/Phenylephrine Clonmel may be associated with a small increased risk of heart attack (myocardial infarction) or stroke. See section 2 "Warnings and precautions".

### **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 national reporting system:

HPRa Pharmacovigilance

Website: [www.hpra.ie](http://www.hpra.ie)

By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Ibuprofen/Phenylephrine Clonmel**

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

Do not use this medicine after the expiry date (EXP) which is stated on the pack. The expiry date refers to the last day of that month.

Do not store above 30°C.

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 Ibuprofen/Phenylephrine Clonmel contains**

The active substances are:

- ibuprofen
- phenylephrine hydrochloride

Each film-coated tablet contains:

- 400 mg ibuprofen
- 10 mg phenylephrine hydrochloride

The other ingredients are:

The core consists of:

- microcrystalline cellulose
- sodium starch glycolate type A
- hypromellose 6 mPa.s
- sodium stearyl fumarate

The film consists of:

- opadry white 200F280000 (consisting of polyvinyl alcohol, talc, macrogol 4000, titanium dioxide (E171), Methacrylic acid – ethyl acrylate copolymer 1:1 (Type A), sodium bicarbonate)

#### **What Ibuprofen/Phenylephrine Clonmel looks like and contents of the pack**

Ibuprofen/Phenylephrine Clonmel 400 mg/10 mg film-coated tablets are white, round, biconvex film coated tablets with a breaking notch on one side and 10 mm diameter. The breaking notch is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

The product is available in cartons of 10, 12, 16, 20, 24 tablets.

#### **Marketing Authorisation Holder and Manufacturer**

##### Marketing Authorisation Holder

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

##### Manufacturer

STADA Arzneimittel AG, Stadastrasse 2-18, D-61118 Bad Vilbel, Germany

STADA Arzneimittel GmbH, Muthgasse 36/2, 1190 Wien, Austria

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

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

[to be completed nationally]

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