

**PACKAGE LEAFLET**

## **PACKAGE LEAFLET: INFORMATION FOR THE USER**

### **Teva Cold Relief 200mg / 30mg Film-coated Tablets**

ibuprofen and pseudoephedrine hydrochloride

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

This medicine is available without prescription. Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.

- **Keep this leaflet.** You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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.
- You must talk to a doctor if you do not feel better or if you feel worse after 3 days in adolescents and 5 days in adults.

#### **What is in this leaflet**

1. What Teva Cold Relief is and what it is used for
2. What you need to know before you take Teva Cold Relief
3. How to take Teva Cold Relief
4. Possible side effects
5. How to store Teva Cold Relief
6. Contents of the pack and other information

This medicine is called Teva Cold Relief 200mg / 30mg film-coated tablets but will be referred to as Teva Cold Relief throughout this leaflet.

#### **1. WHAT Teva Cold Relief IS AND WHAT IT IS USED FOR**

Teva Cold Relief contains the active substances ibuprofen, a non-steroidal anti-inflammatory drug (NSAID), and pseudoephedrine, which is a nasal decongestant.

- Ibuprofen reduces pain, swelling and high temperature.
- Pseudoephedrine acts on the blood vessels in the nose to relieve nasal congestion.

Teva Cold Relief is indicated for the symptomatic relief of nasal congestion with headache, fever and/or pain associated with common colds and flu

Teva Cold Relief is indicated in adults and adolescent over 15 years.

Use this combination product only if you have blocked nose with pain or fever. Do not use this product if you have only one of these symptoms.

Talk to a doctor if you do not feel better or if you feel worse after 3 days in adolescents and 5 days in adults.

#### **2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE Teva Cold Relief**

##### **Do NOT take Teva Cold Relief if you:**

- are allergic to ibuprofen, pseudoephedrine or any of the other ingredients in this medicine (listed in Section 6 and end of Section 2)
- are younger than 15 years
- are pregnant or breast feeding

- have ever had an allergic reaction (such as wheezing, worsening of asthma, itchy runny nose, facial swelling or hives) when previously taking aspirin or other painkillers, other fever-reducing or anti-inflammatory drugs
- have a stomach ulcer or have previously had stomach ulcers,
- have previously had perforation or bleeding related to taking NSAIDs
- have severe liver or kidney failure
- have severe heart failure
- have severe heart or circulation problems (heart disease, high blood pressure, angina, fast heart rate), an overactive thyroid gland, diabetes, phaeochromocytoma (a tumour of the adrenal gland)
- have history of heart attack (myocardial infarction)
- have uncontrolled high blood pressure
- have had a stroke or you are at risk of having a stroke
- have history of seizures
- have any unexplained blood disorders
- have glaucoma (pressure in the eye)
- have difficulty in urinating related to prostate problems
- have Systemic Lupus Erythematosus (LSE), an illness affecting the immune system causing e.g. joint pain and skin changes
- are taking:
  - aspirin (more than 75 mg a day) or other non steroidal anti-inflammatory drugs (NSAIDs) or other painkillers
  - other nasal decongestants as e.g. phenylpropanolamine, phenylephrine or ephedrine or methylphenidate
  - non-selective monoamine oxidase inhibitors (known as MAOIs and used in the treatment of Parkinson's disease or depression) or have taken them in the last 2 weeks

Do NOT give Teva Cold Relief to children under 15 years of age.

### Warnings and precautions

Talk to your doctor or pharmacist **before** taking Teva Cold Relief:

- if you have asthma; risk of an asthma attack
- if you have been told by your doctor that you have a blood clotting disorder
- if you are taking medicines to thin the blood e.g. warfarin, low dose aspirin
- if you are taking medicines which could increase the risk of stomach ulcers or bleeding e.g. steroids, antidepressants of the selective serotonin-reuptake inhibitors (SSRI) class (e.g. fluoxetine, paroxetine) or NSAIDs including aspirin
- if you have high blood pressure, heart problems, heart failure, psychosis or diabetes
- if you have a history of gastrointestinal disease (such as ulcerative colitis or Crohn's disease)
- if you have kidney or liver problems
- if you are taking antimigraine agents.

Medicines such as Teva Cold Relief 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. **Do not exceed the recommended dose or duration of treatment.**

If you have heart problems, previously had a stroke or think that you might be at risk of these conditions (for example if you have high blood pressure, diabetes or high cholesterol, or if you are a smoker) you should discuss your treatment with your doctor or pharmacist.

You should avoid alcohol intake during the treatment.

There is a risk of renal impairment in dehydrated adolescents.

Contact a doctor if symptoms persist or worsen.

## **Children and adolescents**

Teva Cold Relief should not be given to children below 15 years.

## **Other medicines and Teva Cold Relief**

Please tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines, including medicines obtained without a prescription.

Teva Cold Relief must not be used if you are taking:

- aspirin (more than 75 mg a day)
- other non-steroidal anti-inflammatory drugs (NSAIDs)
- other painkillers or fever-reducing drugs
- or have taken in the last 2 weeks monoamine oxidase inhibitors (MAOIs used in the treatment of Parkinson's disease or depression)
- other vasoconstrictor agents used as nasal decongestants (e.g. phenylpropanolamine, phenylephrine and ephedrine, administered orally or nasally).

In particular tell your doctor or pharmacist if you are taking the following as their effects may be changed:

- medicines to thin the blood (anti-coagulants and anti-aggregants) e.g. warfarin or aspirin
- medicines which could increase the risk of stomach ulcers or bleeding e.g. steroids, antidepressants of the SSRI class (e.g. fluoxetine, paroxetine) or NSAIDs including aspirin and cyclo-oxygenase (COX)-2 selective inhibitors
- medicines for high blood pressure, irregular heart rhythm, angina, heart failure or fluid retention (e.g. ACE-inhibitors, betablockers, angiotensin II agonists, cardiac glycosides) because Teva Cold Relief may reduce their effects or increase the risk of abnormal heart rhythm, high blood pressure or impaired kidney function
- cyclosporin (an immunosuppressant) as there may be an increased risk of impaired kidney function
- medicines for depression (lithium, tricyclic antidepressants) may increase the risk of side effects
- concomitant use of phenytoin may increase serum levels of these medicinal products. A check of serum-phenytoin levels is not as a rule required on correct use (maximum over 5 days)
- other decongestants or medicines to reduce appetite as these may increase the risk of side effects
- probenecid or sulfinpyrazone may delay excretion of ibuprofen
- sulphonylureas (antidiabetics): although interactions with ibuprofen have not been described, a check of blood-glucose values is recommended as a precaution on concomitant intake
- medicines to increase urination (diuretics/ water tablets)
- methotrexate in high dose (over 20mg per week), as it may lead to elevated effect of methotrexate
- quinolone antibiotics due to increased risk of developing convulsions
- ciclosporin, tacrolimus and trimethoprim
- anti-migraine agents
- zidovudine (for treating HIV)
- injectable heparin or and preparations containing *Ginkgo biloba* due to increased risk of bleeding.

Due to pseudoephedrine administration an acute hypertensive response may develop in the perioperative period. Therefore, discontinue treatment with Teva Cold Relief several days before surgery and inform your anaesthetist.

## **Teva Cold Relief with food and drink**

Swallow the tablets with water, preferably on a full stomach.

## **Pregnancy, breast-feeding and fertility**

If you are pregnant or breast-feeding or think you might be pregnant or planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Teva Cold Relief must not be taken during pregnancy or if you are breast-feeding. The active ingredients, ibuprofen and pseudoephedrine, can cause serious problems in unborn children and have been shown to be present in breastfed infants of women who have taken them.

Teva Cold Relief contains ibuprofen which belongs to a group of medicines (NSAIDs) which may impair the fertility in women. This effect is reversible on stopping the medicine.

### **Driving and using machines**

Teva Cold Relief has no known effects on the ability to drive and use machines. Dizziness or hallucinations may appear in exceptional cases and this possibility should be taken into account.

### **Teva Cold Relief contains:**

- Sodium – this medicinal product contains 0.28 mg sodium per tablet. To be taken into consideration by those on a controlled sodium diet.

## **3. HOW TO TAKE Teva Cold Relief**

Always take Teva Cold Relief 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.

Teva Cold Relief is for oral use only.

### **The recommended dose is:**

Adults and adolescents aged 15 and over: 1 tablet every 4-6 hours as necessary. For more severe symptoms 2 tablets every 6-8 hours as necessary

Do not exceed the maximum daily dose of 6 tablets.

Swallow the tablets with water, preferably on a full stomach. Do not break or crush the tablets.

### **Use in children and adolescents**

Do not give to children under 15 years of age.

### **Duration of treatment**

This product is intended for short term use only. You should use the lowest dose for the shortest time necessary to relieve your symptoms. Do not take longer than 5 days.

If symptoms persist or worsen, consult your doctor.

If in adolescents this medicinal product is required for more than 3 days, or if symptoms worsen, consult your doctor.

### **If you take more Teva Cold Relief than you should**

**Seek medical advice immediately** if you, or someone else, accidentally take more Teva Cold Relief than is recommended.

### **If you forget to take Teva Cold Relief**

Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this product, ask your pharmacist or doctor.

## **4. POSSIBLE SIDE EFFECTS**

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

**STOP TAKING Teva Cold Relief and seek medical help immediately:**

- if you have any of the following which may be signs of a **severe allergic reaction**:
  - difficulty breathing or swallowing
  - swelling of face, lips, tongue or throat
  - severe itching of the skin with hives (nettle rash)
  - severe skin reactions involving blisters under the skin
  - heart racing with low blood pressure
- if you have signs of intestinal bleeding as
  - bright red faeces (stools/motions), black tarry stools, vomiting blood or dark particles looking like coffee grounds

**Other side effects may include:**

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

- stomach disorders such as abdominal discomfort, indigestion, nausea, vomiting, flatulence, diarrhoea, constipation

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

- headache, dizziness, difficulty in sleeping, agitation, irritability or tiredness
- visual disturbances
- stomach pain or ulcer, sometimes with bleeding or perforation, worsening of colitis and Crohn's disease
- skin rashes

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

- tinnitus
- headache, dizziness and hallucinations
- nervousness, tremor, hallucinations.
- kidney-tissue damage, elevated uric acid concentration in blood

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

- infectious inflammations, symptoms of meningitis (headache, fever, neck stiffness)
- blood disorders (anaemia, leucopenia, thrombocytopenia, pancytopenia, agranulocytosis). First signs are: fever, sore throat, superficial mouth ulcers, flu-like symptoms, severe exhaustion, unexplained bleeding from the nose and bruising
- severe allergic reactions
- psychotic reactions, depression
- kidney failure or other kidney disorders
- liver disorders
- severe skin reactions.

**Reporting of side effects**

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie)

## **5. HOW TO STORE Teva Cold Relief**

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

This medicine does not require any special storage conditions.

Do not use Teva Cold Relief after the expiry date which is stated on the blister/carton after "EXP". The expiry date refers to the last day of that month.

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 to protect the environment.

## **6. CONTENTS OF THE PACK AND OTHER INFORMATION**

### **What Teva Cold Relief contains**

- The **active substances** are ibuprofen (200mg per tablet) and pseudoephedrine hydrochloride (30mg per tablet, equivalent to pseudoephedrine base 24.6 mg)
- The **other ingredients** are  
microcrystalline cellulose, pregelatinised starch (maize), povidone K-30, colloidal anhydrous silica, stearic acid 95, croscarmellose sodium, sodium laurilsulfate, polyvinyl alcohol – part. hydrolyzed, talc (E553b), MICA-based pearlescent pigment (mixture of potassium aluminium silicate (E555)-[mica], titanium dioxide (E171)), polysorbate 80, hypromellose, macrogol 400, yellow iron oxide (E172), red iron oxide (E172), black iron oxide (E172)  
(See end of Section 2 for further information on sodium).

### **What Teva Cold Relief looks like and contents of the pack**

Teva Cold Relief tablets are yellow coloured, oval shaped film-coated tablets (dimension: approx. 15.6 mm x 7.7 mm).

The tablets are available in blister packs of 12, 20 or 24 tablets.

Not all pack sizes may be marketed.

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

#### **Marketing Authorisation Holder**

Procter & Gamble (Health & Beauty Care) Ltd  
The Heights  
Brooklands  
Weybridge  
Surrey  
KT13 0XP  
United Kingdom

#### **Manufacturer(s)**

Merckle GmbH  
Ludwig-Merckle-Strasse 3  
89143 Blaubeuren  
Germany

Teva Czech Industries s.r.o.  
Ostravska 29  
c.p. 305  
74770 Opava-Komarov  
Czech Republic

Teva Operations Poland Sp. z o.o.  
ul. Mogilska 80

31-546, Krakow  
Poland

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

**Italy** Ibuprofene e pseudoefedrina Wick Pharma

**Austria** WICK DayMed Duo

**Czech Republic** Ibuprofen/Pseudoephedrine Hydrochloride

**Germany** WICK DayMed Duo

**Greece** Ibuprofen+Pseudoephedrine/Procter & Gamble

**Spain** MediVicks

**Hungary** Ibuprofen/Pseudoefedrin WICK

**Ireland** Teva Cold Relief 200 mg/30 mg Film-coated Tablets

**Poland** Ibuprofen + Pseudoefedryna 123ratio

**Romania** Tedolfen

**United Kingdom** Ibuprofen and pseudoephedrine hydrochloride

**This leaflet was last revised in November 2014.**