

## PACKAGE LEAFLET: INFORMATION FOR THE USER

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### PANADOL OPTIZORB

500 mg film-coated tablets

PARACETAMOL

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*• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.*

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*• 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 •*

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#### What is in this leaflet?

1. What PANADOL OPTIZORB is and what it is used for
2. Before you take PANADOL OPTIZORB
3. How to take PANADOL OPTIZORB
4. Possible side effects
5. How to store PANADOL OPTIZORB
6. Further information

#### *1. WHAT PANADOL OPTIZORB IS AND WHAT IS IT USED FOR*

PANADOL OPTIZORB Tablets are absorbed faster than regular Paracetamol tablets.

PANADOL OPTIZORB Tablets are used for the relief of headache, tension headache, migraine, backache, rheumatic and muscle pain, toothache and period pain.

They also relieve sore throat and the fever, aches and pains of colds and flu and are recommended for the relief of pain due to mild arthritis.

The active ingredient is paracetamol which is an analgesic (a pain killer that reduces aches and shivers) and antipyretic (it reduces temperature in case of fever).

#### *2. BEFORE YOU TAKE PANADOL OPTIZORB*

#### **Do not take PANADOL OPTIZORB**

- If you are allergic (hypersensitive) to Paracetamol or to any of the other ingredients in this medicine (see section 6).
- If you are taking other painkillers or medicines containing paracetamol.

### **Take special care with PANADOL OPTIZORB**

Tell your doctor if you:

- if you have **liver** or **kidney disease**, including **alcoholic liver disease**
- if you suffer from **mild arthritis** and need to take painkillers every day.

### **Taking other medicines**

Talk to your doctor or pharmacist before taking these tablets if you are taking any prescribed medicines; particularly **metoclopramide** or **domperidone** (for **nausea** [feeling sick] or **vomiting** [being sick]) or **colestyramine** (to lower **blood cholesterol**). If you take **blood thinning drugs (anticoagulants e.g. warfarin)** and you need to take a pain reliever on a daily basis, **talk to your doctor** because of the risk of bleeding.

But you can still take **occasional** doses of Panadol at the same time as anticoagulants.

### **Pregnancy and breastfeeding**

Talk to your doctor before taking Panadol if you are pregnant. You can take this product whilst breast feeding.

### **Driving and using machines**

No specific precautions are required.

### **Important information about some of the ingredients of PANADOL OPTIZORB**

**PANADOL OPTIZORB** tablets contain castor oil-hydrogenated, therefore, you may experience abdominal cramps and diarrhea.

## **3. HOW TO TAKE PANADOL OPTIZORB**

PANADOL OPTIZORB tablets are administered orally.

Adults and children aged 12 years and over:

Swallow 2 tablets every 4 hours as needed.

Do not take more than 8 tablets in 24 hours.

Children aged 6 to 12 years:

Give ½ to 1 tablet every 4 hours as needed.

Do not give more than 4 tablets in 24 hours.

Do not give for more than 3 days at a time unless your doctor tells you to.

- Do not take more frequently than every 4 hours.
- Do not take more than the recommended dose.
- Do not give to children under 6 years.

### **If you take more PANADOL OPTIZORB than you should**

Talk to a doctor at once if you take too much of this medicine even if you feel well. This is because too much paracetamol can cause delayed, serious liver damage.

If your symptoms continue or your headache becomes persistent, **see your doctor**.

Talk to your doctor or pharmacist if you have any additional questions.

## **4. POSSIBLE SIDE EFFECTS**

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

Stop taking the medicine and tell your doctor immediately if you experience:

- Allergic reactions which may be severe such as skin rash and itching sometimes with swelling of the mouth or face or shortness of breath

- Skin rash or peeling, or mouth ulcers
- Breathing problems. These are more likely if you have experienced them before when taking other painkillers such as ibuprofen and aspirin
- Unexplained bruising or bleeding
- Nausea, sudden weight loss, loss of appetite and yellowing of the eyes and skin.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

## 5. HOW TO STORE PANADOL OPTIZORB

Keep out of the reach and sight of children.

This medicine should no longer be used after the expiry date printed on the container and box after "EXP". Store below 30 °C.

## 6. FURTHER INFORMATION

### **What PANADOL OPTIZORB contains**

Each tablet contains 500 mg of paracetamol

The other ingredients are:

Tablet core:

Pregelatinized starch, calcium carbonate, alginic acid, crospovidone, povidone (K-25), magnesium stearate, silica colloidal anhydrous, Parahydroxybenzoates (sodium methyl parahydroxybenzoate (E219), sodium, etilparahidroksibenzoat (E215) and sodium propyl parahydroxybenzoate (E217))

Film coating:

Opadry white (YS-1-7003): titanium dioxide (E171), hypromellose, macrogol 400, polysorbate 80

Carnauba wax

purified water

### **What PANADOL OPTIZORB looks like and contents of the pack**

12 film-coated tablets in blister packs in a box.

White to off white film-coated capsule shaped tablets, with a P debossed on one side and a break line on the other side.

### **Regime of dispensing**

The medicine is issued without doctor's prescription.

### **Manufacturer**

Wellcome Limited, Great West Road 980, Brentford, Middlesex TW8 9GS, England

### **Place of production:**

GlaxoSmithKline Dungarvan Limited, Knockbrack, Dungarvan, Co. Waterford, Ireland

Omega Pharma Manufacturing GmbH & Co. KG, Benzstrasse 25.71083 Herrenberg, Germany

S.C. EUROPHARM S.A., 2 Panselelor St., Brasov, County of Brasov, Romania