

**PACKAGE LEAFLET: INFORMATION FOR THE USER**

# Theraflu<sup>®</sup>

## Extra Strength Cold & Sinus

Powder in sachets for oral solution

Paracetamol 650 mg +  
Phenylephrine hydrochloride 10 mg

Read all of this leaflet carefully because it contains important information for you.  
This medicine is available without prescription. However, you still need to use Theraflu Extra Strength Cold & Sinus 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.
- You must contact a doctor if your symptoms worsen or do not improve.
- If any of the side effects gets serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

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### 1 WHAT THERAFLU EXTRA STRENGTH COLD & SINUS IS AND WHAT IT IS USED FOR

#### What Theraflu Extra Strength Cold & Sinus is

Theraflu Extra Strength Cold & Sinus is a hot liquid medicine that contains a nasal decongestant (phenylephrine) and a pain reliever and fever reducer (paracetamol).

#### What Theraflu Extra Strength Cold & Sinus is used for

Theraflu Extra Strength Cold & Sinus is used to relieve colds and sinus symptoms such as blocked nose (nasal congestion), headache and fever.

### 2. BEFORE YOU TAKE THERAFLU EXTRA STRENGTH COLD & SINUS

#### Do not take Theraflu Extra Strength Cold & Sinus if:

- you are allergic to paracetamol or phenylephrine or any of the ingredients of Theraflu Extra Strength Cold & Sinus (see the list of ingredients at the end of the leaflet, section 6).
- you are taking or have within the past two weeks taken monoamine oxidase (MAO) inhibitor drugs to treat depression. If you do not know if your drug contains a MAO inhibitor, ask a doctor or pharmacist before taking this product.

Tell your doctor or pharmacist if any of the above apply because Theraflu Extra Strength Cold & Sinus is not suitable for you in these circumstances.

#### Take special care with Theraflu Extra Strength Cold & Sinus

**Ask your doctor or pharmacist before taking this medicine if you have any of the following medical problems:**

- you have high blood pressure, heart disease, diabetes, glaucoma (increased eye pressure), kidney or liver disease, thyroid disease, asthma, chronic lung disease, chronic alcoholism or difficulty in urination due to the enlargement of the prostate gland.

#### Prolonged use should only occur on the advice and direction of a doctor.

#### Consult a doctor if:

- the underlying condition requires continued use for more than 5 days (pain), 3 days (fever) or 2 days (severe sore throat),
- you also have a cough that worsens, persists for more than a week or is accompanied by too much phlegm (mucus),
- you have high fever, rash, persistent headache, nausea or vomiting. You should also consult your doctor or pharmacist if you are drinking alcoholic beverages.

#### Taking other medicines

Check with your doctor or pharmacist before taking Theraflu Extra Strength Cold & Sinus if you are taking or have recently taken other medicines, including those obtained without a medical prescription. Especially ask your doctor or pharmacist if you are taking medications containing paracetamol or salicylates.

#### Pregnancy and breast-feeding

If you are pregnant or breast-feeding, you must consult your doctor or pharmacist for advice before taking any medication

#### Elderly population

The elderly should take Theraflu Extra Strength Cold & Sinus only after consultation with a doctor or pharmacist.

#### Driving and using machines

Theraflu Extra Strength Cold & Sinus is not expected to have any effect on your ability to drive or use machines.

### 3. HOW TO TAKE THERAFLU EXTRA STRENGTH COLD & SINUS

For adults and children over 12 years of age: dissolve the contents of one sachet in about 200 ml of hot water. Sweeten to taste if desired. May be repeated every 4 to 6 hours as needed, but do not exceed 4 doses in 24 hours. Theraflu Extra Strength Cold & Sinus should not be used continuously for more than 5 days to relieve your cold symptoms. It is hazardous to exceed the maximum dose unless advised by a doctor.

#### If you take more Theraflu Extra Strength Cold & Sinus than you should.

If you take too much Theraflu Extra Strength Cold & Sinus, contact your doctor or a poison control centre immediately, even if there are no symptoms.

### 4. POSSIBLE SIDE EFFECTS

Like all medicines, Theraflu Extra Strength Cold & Sinus can cause side effects in some people.

**If you notice any of the following side effects, stop using Theraflu Extra Strength Cold & Sinus and tell your doctor or pharmacist immediately:**

- Allergic skin reactions, such as rash or itching.
- Dizziness, nervousness or sleeplessness.

**If any of the side effects gets serious or if you notice any other side effects not mentioned in this leaflet, please tell your doctor or pharmacist.**

### 5. HOW TO STORE THERAFLU EXTRA STRENGTH COLD & SINUS

#### Keep out of the reach and sight of children.

Do not take Theraflu Extra Strength Cold & Sinus after the expiry date which is stated on the pack.

### 6. FURTHER INFORMATION

#### What other ingredients Theraflu contains:

Sucrose, Acesulfame Potassium, D&C Yellow #10, FD&C Yellow #6, Maltodextrin, Silicon Dioxide, Lemon flavours, Citric Acid, Sodium Citrate, Calcium Phosphate.  
Each sachet contains 44 mg of sodium.

#### Manufacturer

Famar Orléans, France for Novartis Consumer Health SA, Nyon, Switzerland

**This leaflet was approved: March 2011**