

## PACKAGE LEAFLET: INFORMATION FOR THE USER

# Cyclo3 cream

Butcher's broom dry extract/Melilot liquid extract

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

If you have any further questions, ask your doctor or pharmacist.

- 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 you notice any side effects not listed in the leaflet, or if any of the side effects gets serious, please tell your doctor or pharmacist.

### In this leaflet:

1. What CYCLO 3, cream is and what it is used for
2. What you need to know before you use CYCLO 3, cream
3. How to use CYCLO 3, cream
4. Possible side effects
5. How to store CYCLO 3, cream
6. Further information

### **1. WHAT CYCLO 3, cream IS AND WHAT IT IS USED FOR**

Traditional herbal medicinal product.

#### **What it is used for**

CYCLO 3, cream is a traditional herbal medicine used to relieve symptoms of discomfort and heaviness of the legs related to minor venous circulatory disturbances. Its use is reserved for the specified indication exclusively based upon long-standing use.

### **2. WHAT YOU NEED TO KNOW BEFORE YOU USE CYCLO 3, cream**

#### **Do not use CYCLO 3, cream:**

- If you are allergic (hypersensitive) to the active

substances (butcher's broom dry extract and/or melilot liquid extract) or to any of the other ingredients in this medicine. A list of ingredients is shown in section 6.

#### **Take special care with CYCLO 3, cream**

- This medicine contains:
  - Sorbic acid, which may cause local skin reactions (e.g. eczema)
  - Methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216), which may cause allergic reactions
- Avoid applying CYCLO 3, cream on damaged skin (sores, skin disease).

#### **You must see a doctor before using this medicine in the following situations:**

- If you have:
  - Inflammation of the skin
  - Inflammation of a vein in which a clot is forming (thrombophlebitis)
  - Dilation and deformation of the superficial veins (varicosis)
  - Rigidity under the skin (subcutaneous induration)
- Ulcers
- Swelling of the legs
- Heart or kidney disease (cardiac or renal insufficiency).

#### **You must consult a doctor:**

- If symptoms worsen or if signs of skin infections occur during the use of the medicine.

#### **Taking other medicines**

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

#### **Pregnancy and breast-feeding**

- This medicine should not be used during pregnancy and while breast-feeding.
- If you discover you are pregnant during treatment, consult your doctor, who alone will be able to judge whether it should be pursued.

Ask your doctor or pharmacist for advice before taking any medicine.

#### **Important information about some of the ingredients of CYCLO 3, cream**

This medicine contains sorbic acid, methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216) (see section «Take special care with CYCLO 3, cream»)

### **3. HOW TO USE CYCLO 3, cream**

Rub in the cream with a light and ascending massage (from the foot towards the knee) for 2 to 3 minutes.

#### **Dosage**

The usual dosage is 2 applications of cream per day. You should check with your doctor or pharmacist if you are not sure.

#### **Method of administration**

This medicine should be applied to the skin.

#### **Duration of treatment**

The duration of treatment is 4 weeks.

See a doctor if symptoms persist for more than 2 weeks.

#### **If you forget to use CYCLO 3, cream**

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

### **4. POSSIBLE SIDE EFFECTS**

Like all medicines, CYCLO 3, cream can cause side effects, although not everybody gets them.

Isolated cases of allergic skin reactions (contact eczema) and local skin reactions such as redness and transient pink or red rash, accompanied by a burning sensation and itching, have been reported with this medicine.

#### **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: Agence nationale de sécurité du médicament et des produits de santé [French National Agency for the Safety of Medicinal and Health Products] (Ansm) and regional pharmacovigilance centre network - website: [www.ansm.sante.fr](http://www.ansm.sante.fr). By reporting side effects, you can help provide more information on the safety of this medicine.

### **5. HOW TO STORE CYCLO 3, CREAM**

Keep out of the sight and reach of children.

Do not use CYCLO 3, cream after the expiry date which is stated on the box. The expiry date refers to the last day of that month.

Do not store above +25°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 to protect the environment.

### **6. FURTHER INFORMATION**

#### **What CYCLO 3, cream contains**

##### **The active substances are:**

Butcher's broom (*Ruscus aculeatus* L.)  
(rhizome dry extract) ..... 16 mg  
Extraction solvent: water  
Herbal substance/native extract ratio: 2.5 – 6.5: 1  
Melilot (*Melilotus officinalis* (L.) Lam.)  
(liquid extract of the aerial parts) ..... 20 mg  
Extraction solvent: ethanol 30% (V/V)  
Herbal substance/final extract ratio: 0.07 – 0.20: 1  
Per 1 g of cream.

##### **The other ingredients are:**

Mixed macrogol stearate, stearic acid, liquid paraffin, sorbic acid, methyl parahydroxybenzoate (E218), purified water, glycerol, propyl parahydroxybenzoate (E216).

#### **What CYCLO 3, cream looks like and contents of the pack**

This medicine is supplied as a cream.

Each box contains one 100 g tube of cream.

#### **Registration Holder / Distributor**

PIERRE FABRE MEDICAMENT  
45 PLACE ABEL GANCE  
92100 BOULOGNE - FRANCE

#### **Manufacturer**

PIERRE FABRE MEDICAMENT PRODUCTION  
45 PLACE ABEL GANCE  
92100 BOULOGNE - FRANCE

#### **This leaflet was last approved revised on 23/12/2013.**

Detailed information on this medicine is available on the ANSM website ([www.ansm.sante.fr](http://www.ansm.sante.fr)).