1.3.2 PATIENT INFORMTION LEAFLET

SCHEDULING STATUS

S5

PROPRIETARY NAME AND DOSAGE FORM

BENCLOPRO 15 Extended release capsule

BENCLOPRO 30 Extended release capsule

Read all of this leaflet carefully before you start taking BENCLOPRO.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **BENCLOPRO** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. WHAT BENCLOPRO CONTAINS

BENCLOPRO 15

The active substance is cyclobenzaprine 15 mg as cyclobenzaprine hydrochloride.

The other ingredients are ethylcellulose, diethyl phthalate, gelatin, hypromellose, polyethylene glycol, red iron oxide, sugar spheres, titanium dioxide and yellow iron oxide

Contains sugar (sucrose in the form of sugar spheres): 109,7 mg.

BENCLOPRO 30

The active substance is cyclobenzaprine 30 mg as cyclobenzaprine hydrochloride.

The other ingredients are ethylcellulose, diethyl phthalate, FD & C Blue No. 1, FD & C Red No. 40, FD&C Yellow No. 6, gelatin, hypromellose, polyethylene glycol, sugar spheres and titanium dioxide

Contains sugar (sucrose in the form of Sugar Spheres): 87,6 mg.

2. WHAT BENCLOPRO IS USED FOR

BENCLOPRO relaxes muscles. It is used along with rest and physiotherapy to decrease muscle pain and spasms associated with strains, sprains or other muscle injuries.

BENCLOPRO should be used only for short periods (up to two or three weeks) because evidence of effectiveness for more prolonged use is not available and because muscle spasm associated with musculoskeletal conditions is generally of short duration.

3. BEFORE YOU TAKE BENCLOPRO

Do not take BENCLOPRO:

- if you are if you are allergic (hypersensitive) to cyclobenzaprine or to any of its other ingredients of **BENCLOPRO** (see **WHAT BENCLOPRO CONTAINS**).
- if you have abnormal heart rhythm (dysrhythmias), heart block conduction disturbances, congestive heart failure or recent heart attack.
- if you have an overactive thyroid (hyperthyroidism).
- if you have been taking a class of antidepressant/ antiparkinson medicines known as monoamine oxidase (MAO) inhibitors.
- if you have liver problems.
- if you are an elderly person.

Take special care with BENCLOPRO:

Tell your doctor or pharmacist:

- if you have severe difficulty in urinating (urinary retention).
- if you have high pressure inside the eyes (glaucoma).

- if you have an exceptionally high fever leading to seizures, and deaths have occurred in patients receiving **BENCLOPRO** concomitantly with MAO inhibitor medicines.
- **BENCLOPRO** is not recommended for use in the elderly. They may be more sensitive to its side effects, especially drowsiness, dizziness, and confusion, which can increase the risk of falling.
- Safety and effectiveness of **BENCLOPRO** has not been established in paediatric (children) patients.

Taking BENCLOPRO with food and drink:

BENCLOPRO may be taken with or without food.

Pregnancy and breastfeeding:

The safety of this medicine during pregnancy and breastfeeding has not been established.

You should not take **BENCLOPRO** if you are pregnant or breastfeeding your baby.

If you are pregnant or breastfeeding your baby, please consult your health care provider for advice before taking this medicine.

Driving and using machinery:

BENCLOPRO may cause dizziness or drowsiness. If you experience dizziness or drowsiness, you should consult your doctor before attempting such activities. Alcohol may worsen dizziness or drowsiness. Limit alcoholic beverages.

Important information about some of the ingredients of BENCLOPRO:

BENCLOPRO contains sucrose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking **BENCLOPRO.**

Taking other medicines with BENCLOPRO:

Always tell your healthcare provider if you are taking, any other medicine. (This includes complementary or traditional medicines.)

Combinations containing any of the following medications, depending on the amount present, may also interact with **BENCLOPRO:**

- Antidepressant/Antiparkinson medication such as MAO inhibitors: Avoid taking MAO inhibitors within 2 weeks before, during, and after treatment with this medication. In some cases, a serious (possibly fatal) medicine interaction may occur.
- Asthma medicines (e.g. salbutanol, salmeterol), cimetidine, clonidine, guanethidine, SSRI antidepressants (e.g. fluoxetine, citalopram), stimulants and weight loss products (e.g. ephedrine, norpseudoephedrine, dextroamphetamine, phenylephrine), tramadol, tricyclic antidepressants (e.g. amitriptyline, imipramine).
- Medicines that cause drowsiness such as: some antihistamines (e.g. diphenhydramine), anti-seizure medicines (e.g. carbamazepine), medicines for sleep or anxiety (e.g. alprazolam, diazepam, zolpidem), muscle relaxants, narcotic pain relievers (e.g. codeine), psychiatric medicines (e.g. chlorpromazine, risperidone, trazodone.

This document does not contain all possible interactions. Therefore, before using this **BENCLOPRO**, tell your doctor or pharmacist of all the products you use. Keep a list of all your medications with you, and share the list with your doctor and pharmacist.

4. HOW TO TAKE BENCLOPRO

Always take BENCLOPRO exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. Do not share medicines prescribed for you with any other person. If you have the impression that the effect of BENCLOPRO is too strong or too weak, talk to your doctor or pharmacist.

The usual dose is one (1) **BENCLOPRO 15** capsule taken once daily.

Doses must be taken at approximately the same time each day. Use of **BENCLOPRO** for periods longer than two or three weeks is not recommended.

Some patients may require up to 30 mg/day, given as one (1) **BENCLOPRO 30** capsule taken once daily or as two (2) **BENCLOPRO 15** capsules taken once daily.

Your doctor will tell you how long your treatment with **BENCLOPRO** will last.

If you take more BENCLOPRO than you should:

If you accidentally take too many tablets, contact your doctor immediately. Symptoms of overdose are drowsiness, rapid heartbeat (tachycardia), tremor, agitation, coma, inability to coordinate voluntary muscular movements (ataxia), high blood pressure (hypertension), slurred speech, confusion, dizziness, nausea, vomiting, and hallucinations, heart attack (cardiac arrest), chest pain, abnormal heartbeats (cardiac dysrhythmias), severe low blood pressure (hypotension) and seizures.

In the event of overdosage, consult your doctor or pharmacist. If neither is available contact the nearest hospital or poison control centre.

If you forget to take BENCLOPRO:

If you forget to take a dose, take the missed dose as soon as you notice it. However, if it is almost time for the next dose, skip the missed dose and continue with your regular dosage schedule. If you miss two or more doses contact your doctor.

Do not take a double dose of **BENCLOPRO** to make up for the forgotten individual doses.

5. POSSIBLE SIDE EFFECTS

BENCLOPRO can have side effects.

Not all side effects reported for BENCLOPRO are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking BENCLOPRO, please consult your healthcare provider for advice.

The following side effects may be experienced while using **BENCLOPRO.**

If any of the following happens, stop taking **BENCLOPRO** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- mental/ mood changes (e.g., confusion, hallucinations), loss of coordination, fainting, seizures
- difficulty urinating, dark urine
- fast/pounding/irregular heartbeat
- stomach/abdominal pain, persistent nausea/vomiting/lack of appetite
- yellowing eyes/skin

Should you experience any of the side effects please tell your doctor as soon as possible:

- any symptoms of a serious allergic reaction, including: rash, itching, swelling, severe dizziness, trouble breathing.

These are the frequent reported side effects, should you experience any of the side effects please tell your doctor:

- drowsiness, dry mouth, fatigue, dizziness, lightheadedness, constipation, or blurred vision.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

6. STORING AND DISPOSING OF BENCLOPRO

- Store at or below 25 ºC in original packaging.
- *HDPE bottles*: Keep in the original container. Keep container well closed.
- *Blister packs:* Keep the blisters in the carton until required for use.
- **STORE ALL MEDICINES OUT OF REACH OF CHILDREN**.
- ***Do not store in bathrooms.***

- ***Do not use after the expiry date stated on the label or carton.***
- ***Return all unused medicine to your pharmacy.***
- ***Do not dispose of unused medicine in drains or sewerage systems e.g. toilets.***

7. PRESENTATION OF BENCLOPRO

White HDPE bottles with white polypropylene caps containing 30 capsules per bottle.

Blister packs consisting of PVC forming film and Aluminium lidding material containing 15 capsules per card.

8. IDENTIFICATION OF BENCLOPRO

BENCLOPRO 15: Light orange opaque, hard gelatin body with blue ink imprint "1002-15" and Light Orange opaque cap with blue ink imprint "EUR" containing spherical beads that are white to yellow in colour.

BENCLOPRO 30: Dark blue opaque, hard gelatin body with white ink imprint "1002-30" and red opaque hard gelatin cap with white ink imprint "EUR" containing spherical beads that are white to yellow in colour.

9. REGISTRATION NUMBER

BENCLOPRO 15: 57/17.1/0701

BENCLOPRO 30: 57/17.1/0702

10. NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF HOLDER OF THE CERTIFICATE OF REGISTRATION

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11. DATE OF PUBLICATION

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