**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.



Date of Approval: 21 February 2023

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 allergic (hypersensitive) to cyclobenzaprine or to any of the 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. salbutamol, 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 **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 capsules, 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

Date of registration: 21 February 2023

**SKEDULERINGSTATUS**

**S5**

**EIENDOMSNAAM EN DOSERINGSVORM**

**BENCLOPRO 15** verlengde vrystelling kapsule

**BENCLOPRO 30** verlengde vrystelling kapsule

**Lees hierdie hele biljet noukeurig deur voordat u begin om BENCLOPRO te neem.**

- Hou hierdie biljet. U sal dit dalk weer moet lees.
- Indien u verdere vrae het, raadpleeg asseblief u dokter of u apteker.
- **BENCLOPRO** is aan u persoonlik voorgeskryf en u moenie u medisyne met ander mense deel nie. Dit kan hulle benadeel, selfs al ervaar hul dieselfde simptome as u.

## 1. WAT BENCLOPRO BEVAT

**BENCLOPRO 15**

Die aktiewe bestanddeel is siklobensaprien 15 mg as siklobensaprienhidrochloried.

Die ander bestanddele is etielsellulose, dietielftalaat, gelatien, hipromellose, poliëtileenglikol, rooi ysteroksied, suikersfere, titaandioksied en geel ysteroksied.

Bevat suiker (sukrose in die vorm van suikersfere): 109,7 mg.

**BENCLOPRO 30**

Die aktiewe bestanddeel is siklobensaprien 30 mg as siklobensaprienhidrochloried.

Die ander bestanddele is etielsellulose, diethielftalaat, FD & C Blou No. 1, FD & C Rooi No. 40, FD&C Geel No. 6, gelatien, hipromellose, poliëtileenglikol, suikersfere en titaandioksied.

Bevat suiker (sukrose in die vorm van suikersfere): 87,6 mg.

## 2. WAARVOOR BENCLOPRO GEBRUIK WORD

**BENCLOPRO** ontspan spiere. Dit word saam met rus en fisioterapie gebruik om spierpyn en spasmas te verminder, wat verband hou met swikking, verstuitings of ander spierbeserings. **BENCLOPRO** moet slegs vir kort tydperke (vir twee of drie weke) gebruik word, omdat bewyse van doeltreffendheid vir gebruik oor langer tydperke nie beskikbaar is nie, en omdat spierspasma wat verband hou met muskuloskeletale toestande oor die algemeen van korte duur is.

## 3. VOORDAT U BENCLOPRO NEEM

**Moenie BENCLOPRO neem nie:**

- indien u allergies (hipersensitief) is vir siklobensaprien of vir enige van die ander bestanddele van **BENCLOPRO** (sien **WAT BENCLOPRO BEVAT**).
- indien u abnormale hartritme (disritmie), hartblokgeleidingsversteurings of kongestiewe hartversaking het, of ‘n onlangse hartaanval gehad het.
- indien u 'n ooraktiewe skildklier (hipertireose) het.
- Indien u 'n klas antidepressante/antiparkinsonisme-medisyne gebruik het, bekend as monoamienoksidase (MAO) inhibeerder.
- indien u lewerprobleme het.
- indien u 'n bejaarde persoon is.

**Wees veral versigtig met BENCLOPRO:**

***Lig u dokter of apteker in:***

- indien u ernstige probleme ondervind om te urineer (urienretensie).
- indien u hoë druk in die oë het (gloukoom).
- indien u 'n buitengewone hoë koors het wat tot stuipaanvalle lei; sterftes het voorgekom in pasiënte wat **BENCLOPRO** gelyktydig met MAO-inhibeerder medisyne ontvang.
- **BENCLOPRO** word nie aanbeveel vir gebruik by bejaardes nie. Hulle kan meer sensitief

wees vir die newe-effekte daarvan, veral slaperigheid, duiseligheid en verwarring, wat die risiko van val kan verhoog.

- Veiligheid en doeltreffendheid van **BENCLOPRO** is nie by pediatriese pasiënte (kinders) vasgestel nie.

**Die neem van BENCLOPRO saam met kos en drank:**

**BENCLOPRO** kan met of sonder kos geneem word.

**Swangerskap en borsvoeding:**

Die veiligheid van hierdie medisyne tydens swangerskap en borsvoeding is nie vasgestel nie.

U moet nie **BENCLOPRO** neem indien u swanger is of u baba borsvoed nie.

**Indien u swanger is of u baba borsvoed, raadpleeg asseblief u gesondheidsorgverskaffer vir advies voordat u hierdie medisyne neem.**

**Bestuur en gebruik van masjinerie:**

**BENCLOPRO** kan duiseligheid of slaperigheid veroorsaak. Indien u duiseligheid of slaperigheid ervaar, moet u u dokter raadpleeg voordat u sulke aktiwiteite aanpak. Alkohol kan duiseligheid of slaperigheid vererger. Beperk alkoholiese drankies.

**Belangrike inligting oor sommige van die bestanddele van BENCLOPRO:**

**BENCLOPRO** bevat sukrose wat 'n uitwerking op die beheer van u bloedsuiker kan hê indien u diabetes mellitus het.

Indien u deur u dokter meegedeel is dat u 'n onverdraagsaamheid teenoor sommige suikers het, kontak u dokter voordat **BENCLOPRO** geneem word.

**Die neem van ander medisyne saam met BENCLOPRO:**

Lig altyd u gesondheidsorgverskaffer in indien u enige ander medisyne neem. (Dit sluit komplementêre of tradisionele medisyne in.)

Kombinasies wat enige van die volgende medikasie bevat, afhangende van die hoeveelheid teenwoordig, kan ook interaksie met **BENCLOPRO** hê:

- Antidepressante/Antiparkinsonisme-medikasie soos MAO-inhibeerders: Vermy MAO-inhibeerders binne 2 weke voor, tydens en ná behandeling met hierdie medikasie. In sommige gevalle kan 'n ernstige (moontlik dodelike) medisyne-interaksie voorkom.
- Asma-medisyne (bv. salbutamol, salmeterol), simetidien, klonidien, guanetidien, SSHI-antidepressante (bv. fluoksetien, sitalopraam), stimulante en gewigsverliesprodukte (bv. efedrien, norpseudoefedrien, dekstro-amfetamien, fenielefrien), tramadol, trisikliese antidepressante (bv. amitriptilien, imipramien).
- Medisyne wat lomerigheid veroorsaak, soos sommige antihistamiene (bv. difenhidramien), medisyne teen stuipaanvalle (bv. karbamasepien), medisyne vir slaap of angs (bv. alprasolaam, diasepaam, zolpidiem), spierverslappers, narkotiese pynstillers (bv. kodeïen), psigiatriese medisyne (bv. chloorpromasien, risperidoon, trasodoon).

Hierdie dokument bevat nie alle moontlike interaksies nie. Daarom, voordat u **BENCLOPRO** gebruik, lig u dokter of apteker in van al die produkte wat u gebruik. Hou 'n lys van al u medikasie by u, en deel die lys met u dokter en apteker.

## 4. HOE OM BENCLOPRO TE NEEM

**Neem BENCLOPRO altyd presies soos u dokter u opdrag gegee het. U moet met u dokter of apteker nagaan indien u onseker is. Moenie medisyne wat aan u voorgeskryf is, met enige ander persoon deel nie. Indien u die indruk het dat die effek van BENCLOPRO te sterk of te swak is, raadpleeg u dokter of apteker.**

Die algemene dosis is een (1) **BENCLOPRO 15** kapsule wat een keer per dag geneem word. Dosisse moet elke dag op ongeveer dieselfde tyd geneem word. Gebruik van **BENCLOPRO** vir tydperke langer as twee of drie weke word nie aanbeveel nie.

Sommige pasiënte kan tot 30 mg/dag benodig, gegee as een (1) **BENCLOPRO 30** kapsule wat een keer per dag geneem word, of as twee (2) **BENCLOPRO 15** kapsules wat een keer per dag geneem word.

U dokter sal u vertel hoe lank u behandeling met **BENCLOPRO** sal duur.

**Indien u meer BENCLOPRO neem as wat u moes:**

Indien u per ongeluk te veel kapsules neem, kontak u dokter dadelik. Simptome van oordosis is lomerigheid, vinnige hartklop (tagikardie), bewing, agitasie, koma, onvermoë om vrywillige spierbewegings te koördineer (ataksie), hoë bloeddruk (hipertensie), onduidelike spraak, verwarring, duiseligheid, naarheid, braking en hallusinasies, hartaanval (hartstilstand), borspyn, abnormale hartklop (hartdisritmie), ernstige lae bloeddruk (hipotensie) en stuipaanvalle.

**In die geval van oordosering, raadpleeg u dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifhulpsentrum.**

**Indien u vergeet om BENCLOPRO te neem:**

Indien u vergeet om 'n dosis te neem, neem die oorgeslaande dosis sodra u dit opmerk. Indien dit egter amper is tyd vir die volgende dosis, slaan die dosis wat gemis is, oor en gaan voort met u gereelde doseringskedule. Indien u twee of meer dosisse mis, kontak u dokter.

Moenie 'n dubbele dosis **BENCLOPRO** neem om op te maak vir die vergete individuele dosisse nie.

## 5. MOONTLIKE NEWE-EFFEKTE

**BENCLOPRO** kan newe-effekte hê.

**Nie alle newe-effekte wat vir BENCLOPRO aangemeld is, word in hierdie biljet ingesluit nie. Indien u algemene gesondheid verswak of indien u enige ongewenste effekte ervaar terwyl u BENCLOPRO neem, raadpleeg asseblief u gesondheidsorgverskaffer vir advies.**

Die volgende newe-effekte kan ervaar word tydens die gebruik van **BENCLOPRO.**

Indien enige van die volgende gebeur, staak **BENCLOPRO** en lig u dokter dadelik in, of gaan na die ongevalle-afdeling by u naaste hospitaal:

- geestelike/gemoedsveranderinge (bv. verwarring, hallusinasies), verlies aan koördinasie, floute, stuipaanvalle
- probleme met urinering, donker urien
- vinnige/harde/onreëlmatige hartklop
- maag-/buikpyn, aanhoudende naarheid/braking/gebrek aan eetlus
- vergeling van oë/vel

Indien u enige van die newe-effekte ervaar, lig asseblief u dokter so gou as moontlik in:

- enige simptome van 'n ernstige allergiese reaksie, insluitend: veluitslag, jeukerigheid, swelling, erge duiseligheid, probleme met asemhaling.

Hierdie is die newe-effekte wat gereeld aangemeld is, indien u enige van die newe-effekte ervaar, lig asseblief u dokter in:

- lomerigheid, droë mond, moegheid, duiseligheid, lighoofdigheid, hardlywigheid of versteurde visie.

Indien u enige newe-effekte opmerk wat nie in hierdie biljet genoem word nie, stel asseblief u dokter of apteker in kennis.

## 6. BERGING EN WEGDOENING VAN BENCLOPRO

- Bêre teen of benede 25 ºC in oorspronklike verpakking.
- *HDPE-bottels:* Hou in die oorspronklike houer. Hou houer dig toe.
- *Stulpstrookverpakkings*: Hou die stulpstroke in die karton tot benodig vir gebruik.
- **BÊRE ALLE MEDISYNE BUITE BEREIK VAN KINDERS.**
- Moenie in badkamers bêre nie.
- Moenie gebruik ná die vervaldatum wat op die etiket of kartonboksie gedruk is nie.
- Neem alle ongebruikte medisyne terug na u apteek.
- Moenie ongebruikte medisyne in afvoerpype of rioolstelsels weggooi nie, bv. toilette.

## 7. AANBIEDING VAN BENCLOPRO

Wit HDPE-bottels met wit polipropileendoppies wat 30 kapsules per bottel bevat.
Stulpstrookverpakkings wat bestaan uit PVC-vormingsfilm en aluminium bedekkingsmateriaal wat 15 kapsules per kaart bevat.

## 8. IDENTIFIKASIE VAN BENCLOPRO

**BENCLOPRO 15:** Lig-oranje ondeursigtige, harde gelatienbasis met "1002-15" in blou ink gedruk, en lig-oranje ondeursigtige dop met "EUR" in blou ink gedruk, wat sferiese korrels bevat wat wit tot geel van kleur is.
**BENCLOPRO 30:** Donkerblou ondeursigtige, harde gelatienbasis met "1002-30" in wit ink gedruk, en rooi ondeursigtige harde gelatiendop met "EUR" in wit ink gedruk, wat sferiese korrels bevat wat wit tot geel van kleur is.

## 9. REGISTRASIENOMMER

**BENCLOPRO 15:** 57/17.1/0701

**BENCLOPRO 30:** 57/17.1/0702

## 10. NAAM, BESIGHEIDSADRES EN TELEFOONNOMMER VAN DIE HOUER VAN DIE SERTIFIKAAT VAN REGISTRASIE

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## 11. DATUM VAN PUBLIKASIE

Datum van registrasie: 21 Februarie 2023

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