SCHEDULING STATUS: S5

SYNALEVE CAPSULES, 200 mg/8 mg/400 mg, capsules

Meprobamate, codeine phosphate, paracetamol

Sugar free

Read all of this leaflet carefully before you start taking SYNALEVE CAPSULES

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- SYNALEVE CAPSULES 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.

What is in this leaflet

1. What SYNALEVE CAPSULES is and what it is used for
2. What you need to know before you take SYNALEVE CAPSULES
3. How to take SYNALEVE CAPSULES
4. Possible side effects
5. How to store SYNALEVE CAPSULES
6. Contents of the pack and other information

1. What SYNALEVE CAPSULES is and what it is used for

SYNALEVE CAPSULES contains active ingredients paracetamol, codeine phosphate and meprobamate.

SYNALEVE CAPSULES can be used for the relief of pain, and pain associated with tension or strain.

2. What you need to know before you take SYNALEVE CAPSULES

Do not take SYNALEVE CAPSULES:

- if you are hypersensitive (allergic) to meprobamate, codeine phosphate, paracetamol or any of the other ingredients of SYNALEVE CAPSULES (listed in section 6),
- if you have liver or kidney problems,
- if you have asthma, bronchitis or breathing problems,
- if you have had a recent head injury or if you have a condition in which the pressure in your skull has increased,
- if you have just had an operation on your bile tract,
- if you are drinking large quantities of alcohol on a regular basis
- if you have heart failure caused by chronic lung disease,
- if you have porphyria (a disorder resulting from the build-up of certain chemicals related to red blood cell proteins),
- if you are taking an antidepressant in the class called monoamine oxidase inhibitors or within 14 days of stopping such treatment,
- if your child (the patient) is under 12 years old,
- if you are breastfeeding,
- if you are in the third trimester of pregnancy,
- for pain relief in children and adolescents (0-18 years of age) after removal of tonsils or adenoids due to obstructive sleep apnoea syndrome.

Warnings and precautions

Take special care with SYNALEVE CAPSULES:

Paracetamol:

- If you have liver or kidney problems, your doctor should monitor you more closely.

- Serious skin reactions such as toxic epidermal necrolysis (TEN), Stevens-Johnson syndrome (SJS), acute generalized exanthematous pustulosis (AGEP), drug reaction with eosinophilia and systemic symptoms (DRESS)/Drug-induced hypersensitivity syndrome (DIHS) and fixed drug eruptions (FDE) have been reported in patients receiving paracetamol. If you/your child experience any signs of serious skin reactions such as swelling, itching, red severe rash, stop using SYNALEVE CAPSULES immediately and contact your doctor (see section 4).

Codeine phosphate:

SYNALEVE CAPSULES contains codeine phosphate, which is an opioid medicine. Repeated use of SYNALEVE CAPSULES may result in you becoming accustomed to it (needing to take higher doses). Repeated use of SYNALEVE CAPSULES may also lead to dependence, abuse and addiction, which may result in life-threatening overdose.
If you experience any of the following signs whilst taking SYNALEVE CAPSULES, talk to your doctor or pharmacist as it could be an indication that you are dependent or addicted.

- **You need to take this medicine for longer than advised**
- **You need to take more than the recommended dose**
- **You are using this medicine for reasons other than medical reasons, for instance, 'to stay calm' or to 'help you sleep'**
- **You have made repeated, unsuccessful attempts to quit or control the use of this medicine**
- **When you stop taking this medicine you feel unwell, and you feel better once taking this medicine again ('withdrawal effects').**

There is an increased risk of addiction in patients with personal or family history of substance abuse or mental health disorders.

- *Opioid Induced Hyperalgesia*

  Taking high doses of opioid medications can paradoxically induce or sensitise patients to acute pain, this condition is called opioid-induced hyperalgesia. The type of pain experienced might be the same or different from the original underlying pain, and in some cases, patients may experience pain from ordinarily non-painful stimuli (allodynia).
- If you have an under active thyroid gland (a condition where the thyroid gland does not produce enough hormones),
- if you have adrenocortical insufficiency (a condition where the adrenal glands do not produce enough steroid hormone),
- if you have impaired liver function,
- if you have an enlarged prostate gland,
- if you are in shock (a condition where there is not enough blood flow through the body),
- if you have inflammatory or obstructive bowel disorders (a problem or blockage of your bowel),
- If you are an elderly or disabled, the dosage of SYNALEVE CAPSULES should be carefully considered.

Meprobamate:

- If you have been taking meprobamate for an extended period of time, or in high doses, the discontinuation of SYNALEVE CAPSULES should be gradual and slow,
- meprobamate may affect how other medications are metabolized in our bodies, especially medications that are metabolized by liver enzymes, it is important to mention if you are using any of other medicines,
- if you have a history of epilepsy, meprobamate may cause seizures/ convulsions,
- if you show early warning signs before psychosis (mental state of feeling disconnected from reality), the use of SYNALEVE CAPSULES should be used with caution as you have a higher chance to develop dependence of meprobamate and codeine phosphate,

- if you do not experience enough relief of pain with the prescribed dose, please consult with your doctor, as higher dosages than recommended can lead to serious liver damage,
- meprobamate may cause sleepiness and may lower your ability to concentrate, you should be cautious in situations where a weakened concentration could lead to accidents (see section 2, Driving and using machines),
- meprobamate should not be used continuously for longer than 10 days without consulting your doctor.

Children and adolescents

Do not give SYNALEVE CAPSULES to children under 12 years of age (refer to section 2, Do not take SYNALEVE CAPSULES).

Use in children with breathing problems:

Codeine is not recommended in children with breathing problems, since the symptoms of morphine toxicity may be worse in these children.

Other medicines and SYNALEVE CAPSULES

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

Your doctor may want to check that your medicines are working properly if you are taking:

- Monoamine oxidase inhibitors (usually used to treat depression), if you are using this medication or have used it within the past 14 days,
- Alcohol or other central nervous system depressants (e.g. calming or tranquilizing medications) may lead to increased side effects such as drowsiness and impaired concentration,
- Codeine and other central nervous system depressants namely anaesthetics (medications used during and after surgical operations), hypnotics (sleeping pills), sedatives (used to treat

conditions like anxiety and sleep disorders) and phenothiazines (antipsychotic medicine) may cause a lowered functioning and slower activity of the brain,

- Meprobamate (an active ingredient in SYNALEVE CAPSULES) may lower your ability to tolerate taking large quantities of alcohol,
- Meprobamate may lower your ability to tolerate the use of other medications that also have central nervous system depressing effects (slow down brain activity).

SYNALEVE CAPSULES with alcohol

Do not drink alcohol whilst taking SYNALEVE CAPSULES. Alcohol may make you feel more drowsy and further impair your concentration.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

SYNALEVE CAPSULES is not recommended for use during early pregnancy and is contraindicated in the third trimester of pregnancy.

SYNALEVE CAPSULES is contraindicated in breastfeeding women.

No data on the influence of fertility is available.

Driving and using machines

SYNALEVE CAPSULES may lead to drowsiness and impaired concentration and you should not drive vehicles or operate machines where loss of attention could lead to accidents (see section 2, Warnings and precautions, as well as section 4, Possible side effects).

It is not always possible to predict to what extent SYNALEVE CAPSULES may interfere with the daily activities of a patient. Patients should ensure that they do not engage in tasks or activities requiring mental alertness, judgement and / or sound coordination and vision until they are aware

of the measure to which SYNALEVE CAPSULES affects them.

3. How to take SYNALEVE CAPSULES

Do not share medicines prescribed for you with any other person:

Always take SYNALEVE CAPSULES exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

DO NOT EXCEED THE RECOMMENDED DOSE.

The usual dose for adults and children over the age of 12 years is:

One to two (1 or 2) capsules three to four (3 to 4) times a day, if necessary.

Do not exceed eight (8) capsules per day.

Your doctor will tell you how long your treatment with SYNALEVE CAPSULES will last. If you have the impression that the effect of SYNALEVE CAPSULES is too strong or too weak, tell your doctor or pharmacist.

If you take more SYNALEVE CAPSULES than you should

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

Prompt medical attention is critical. Even if you do not show symptoms of an overdose, immediately go to your nearest hospital or Poison Centre.

SYNALEVE CAPSULES contains paracetamol and an overdose can be fatal.

The symptoms of an overdose can include nausea, stomach pain, loss of appetite, vomiting (may be blood streaked), ringing in the ears, excitement, convulsions (mainly in children), and breathing problems.

If you forget to take SYNALEVE CAPSULES

Do not take a double dose to make up for forgotten individual doses.

If you stop taking SYNALEVE CAPSULES

When you have been taking meprobamate for some time now, or in high doses, the discontinuation of meprobamate should be gradual and slow, (see section 2, Warnings and precautions).

4. Possible side effects

SYNALEVE CAPSULES can have side effects.

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

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

- severe hypersensitivity reactions that present as more severe with angioneurotic oedema (swelling under the skin), bronchospasm (narrowing and obstruction of the respiratory airway) or anuria (failure of the kidneys to produce urine).
- Mouth ulcers, cold sores and ulcers or soreness of your tongue.
- Skin lumps or hives (raised, red or white, itchy patches of skin).
- Blisters on your skin or inside your mouth, nose, vagina or bottom.
- The appearance of a rash or sunburn when you have been outside (even on a cloudy day).
- Swelling of the eyelids, face, tongue or lips.
- Severe dizziness.
- Difficulty in breathing.

- Serious skin reactions such as swelling, itching, red severe rash especially those covering your whole body (appearing as allergic wheels).

These are all very serious side effects. If you have them, you may have had a serious reaction to SYNALEVE CAPSULES. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- chest pain,
- changes in the way your heart beats, for example, if you notice it is beating faster,
- worsening of a condition namely porphyria, (signs of severe stomach pain, pain in chest, legs or back, muscle pain).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following side effects:

Paracetamol

- Sensitivity reactions, usually in the form of skin rashes (which will disappear if you stop using SYNALEVE CAPSULES,
- changes in your blood counts and cells.

Codeine phosphate

- Pruritus (itching) and urticaria (hives or rash of the skin),
- mood changes, restlessness,
- sleepiness,
- increased pressure in your skull,
- small pupils (miosis),
- a sudden drop in blood pressure when you stand up (orthostatic hypotension),
- low body temperature,

- nausea, vomiting, constipation,
- difficulty in emptying your bladder,
- pain in your liver and/or gallbladder (biliary spasm).

Less frequent:

- Abdominal pain including risk of inflammation of pancreas, which causes severe pain in the abdomen and back.

Meprobamate

- Low blood cell counts (aplastic anaemia, leucopoenia, thrombocytopenia, agranulocytosis),
- paraesthesia (pins and needles),
- ataxia (slurred speech and incoordination),
- headache,
- excitement,
- feeling of dizziness,
- improper eye sight,
- low blood pressure,
- nausea or vomiting (feeling sick), diarrhoea.

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

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the Med Safety App (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.
For reporting of side effects directly to the HCR, contact +27 11 635 0134 or email Adcock.aereports@adcock.com.

By reporting these side effects, you can help provide more information on the safety of SYNALEVE CAPSULES.

5. How to store SYNALEVE CAPSULES

Store all medicines out of reach of children.

- Store in a well-closed container at or below 25 °C,
- protect from light,
- do not use after the expiry date stated on the label, carton or bottle,
- return all unused medicine to your pharmacist,
- do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What SYNALEVE CAPSULES contains

The active substances are meprobamate, codeine phosphate and paracetamol.

The other ingredients are

Capsule fill

Purified talc

Capsule body

Erythrosin CI 45430

Gelatin

Titanium Dioxide CI 77891

Quinoline Yellow CI 47005

Capsule cap

Gelatin

Indigo Carmine CI 73015

Titanium Dioxide CI 77891

Constituents of the black printing ink on capsule

Opacode Black S-1-27794:

Industrial Methylated Spirit 74 OP

Iron Oxide Black (CI # 77499)

Isopropyl Alcohol

N-Butyl Alcohol

Propylene Glycol

Purified Water

Shellac Glaze-47,5 % (22 % Esterified) in IMS 74 OP

Or

TekPrint SW-9008 Black Ink:

Black Iron Oxide E172

Butyl Alcohol

Dehydrated Alcohol

Isopropyl Alcohol

Potassium Hydroxide

Propylene Glycol

Purified Water

Shellac

Strong Ammonia Solution

What SYNALEVE CAPSULES looks like and contents of the pack

SYNALEVE CAPSULES: Size ‘0' and/or ‘0E’, elongated, hard gelatin capsule with powder blue, opaque cap and ivory, opaque body with "SYNALEVE" imprinted on both the cap and the body.

Content of the packaging:

Blister packs of 20, 40 and 100 capsules.

Containers of 100 and 500 capsules.

Capsules packed in 20’s:

20’s (2 X 10) Blister pack using aluminium foil and clear PVC Cello.

Capsules packed in 40’s:

40’s (4 X 10) Blister pack using PVC film and printed aluminium foil.

Capsules packed in 100’s:

- 100’s Securitainer with closure and wadding foam.
- 100’s White cylindrical screw type HDPE container with screw cap.
- 100’s (10 X 10) Blister pack using PVC film and printed aluminium foil.

Capsules packed in 500’s:

- 500’s White PVC jar with an HDPE screw cap and foam insert.

Not all pack types and pack sizes may be marketed.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information Leaflets:

https://www.sahpra.org.za/pi-pil-repository/

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