Patient information leaflet for LESSMUSEC

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S2

LESSMUSEC, 375 mg capsules, hard
Carbocisteine
Sugar free.

Read all of this leaflet carefully because it contains important information for you.
LESSMUSEC is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use LESSMUSEC carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share LESSMUSEC with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.

What is in this leaflet

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

1. What LESSMUSEC is and what it is used for

LESSMUSEC contains carbocisteine, which belongs to a group of medicines called mucolytics, which causes your mucus to be less sticky and easier to cough up.
LESSMUSEC is used to help treat respiratory tract problems (problems with your breathing passages), characterised by too much sticky mucus, in the absence of infection.

2. What you need to know before you take LESSMUSEC

Do not take LESSMUSEC:

- if you are hypersensitive (allergic) to carbocisteine or any of the other ingredients of LESSMUSEC (listed in section 6).
- if you have an active peptic (stomach) ulcer, characterised by burning stomach pain, heartburn, nausea, feeling full or bloated.

Warnings and precautions
Take special care with LESSMUSEC:

- if you are elderly.
- if you have had a peptic (stomach) ulcer in the past.
- if you are taking medicines known to cause bleeding in your stomach or intestines (gastrointestinal bleeding), such as nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g. diclofenac and ibuprofen), acetylsalicylic acid, clopidogrel, prasugrel, heparin, warfarin and other medicines used to prevent and treat blood clots. Stop taking LESSMUSEC and contact your doctor if you experience gastrointestinal bleeding (characterised by black or tarry stools, dark or bright red blood mixed with your stool, bright red blood in your vomit or stomach pain).
- if you have problems with your thyroid gland (an underactive thyroid gland, causing a decrease in metabolism. Symptoms include feeling tired and lethargic, muscle weakness, cramps, feeling cold, a slow heart rate, dry and flaky skin, hair loss, a deep and husky voice and weight gain).

Children
No information available.

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

The following medicine may cause an interaction with LESSMUSEC:
Pholcodine linctus (cough mixture, used to suppress cough).

LESSMUSEC with food and drink
See section 3.

Pregnancy and breastfeeding
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 LESSMUSEC.

Safety and efficacy during pregnancy and breastfeeding have not been established. Therefore, the use of LESSMUSEC during pregnancy and breastfeeding is not recommended.

Driving and using machines
LESSMUSEC is not likely to impair your ability to drive a vehicle or use machines. Take special care before driving a vehicle or operating any machines requiring your attention, until you know how LESSMUSEC will affect you.

LESSMUSEC contains Sunset Yellow FCF (E110), ponceau 4R (E124) and carmoisine (E122)
LESSMUSEC contains Sunset Yellow FCF (E110), ponceau 4R (E124) and carmoisine (E122) (colourants), which may cause allergic reactions.

3. How to take LESSMUSEC

Do not share medicines prescribed for you with any other person.
Always take LESSMUSEC exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.
LESSMUSEC is for oral use only.
The usual adult dose is 2 capsules 3 times a day, reducing to 1 capsule 4 times a day until a satisfactory response is seen.
If you have the impression that the effect of LESSMUSEC is too strong or too weak, tell your doctor or pharmacist.

If you take more LESSMUSEC than you should
In the event of an overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

An upset stomach (gastrointestinal disturbance) is the most likely symptom of LESSMUSEC overdosage.

If you forget to take LESSMUSEC
Take the missed dose as soon as you remember. If it is almost time for your next dose, do not take the missed dose but simply take your next dose at the normal time.
Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

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

If any of the following happens, stop taking LESSMUSEC and tell your doctor immediately or go to the casualty department at your nearest hospital:
- swelling of your hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching;
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to LESSMUSEC. 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:

- changes in the way your heart beats, for example, if you notice it beating faster or irregular;
- serious skin rashes;
- Stevens-Johnson syndrome (characterised by severe blisters and bleeding in your lips, eyes, mouth, nose and genitals);
- Erythema multiforme (characterised by red, often itchy spots, similar to the rash of measles, which start on your limbs and sometimes on your face and the rest of your body. The spots may blister or progress to form raised, red, pale-centred marks. You may also experience fever, sore throat, headache and/or diarrhoea);
- bleeding from your intestine or stomach (which may be seen as black, tar-like stools).

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

Tell your doctor if you notice any of the following:
Side effects with unknown frequency:

- dizziness, headache;
- nausea (feeling sick), vomiting (being sick), heartburn, diarrhoea, stomach discomfort.

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. You can also report side effects to SAHPRA via the **6.04 Adverse Drug Reaction Reporting Form**, found online **under SAHPRA's publications**: https://www.sahpra.org.za/Publications/Index/8.
By reporting side effects, you can help provide more information on the safety of LESSMUSEC.

5. How to store LESSMUSEC

- Store all medicine out of reach of children.
- Store at or below 25 °C.
- Protect from light and moisture.
- Keep container tightly closed until required for use.
- Do not use after the expiry date stated on the container.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What LESSMUSEC contains
Each capsule contains 375 mg of the active substance, carbocisteine.

The other ingredients are colourants (carmoisine (E122), erythrosine (E127), ponceau 4R (E124), Sunset Yellow FCF and titanium dioxide), gelatine, magnesium stearate, maize starch and purified talc.

What LESSMUSEC looks like and contents of the pack
Red cap and orange body, size 0 capsule.

White HDPE cylindrical securitainer with a white HDPE snap-on cap. The container also includes a desiccant.
OR
2,5 litre white polypropylene bucket lined with a plastic bag (polyethylene) with a white polypropylene push-on lid. The bucket also includes a desiccant.
Pack sizes: 20, 30 or 1 000 capsules.
Not all pack sizes may be marketed.

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