Applicant/HCR	sanofi-aventis south africa (pty) ltd
Product name, strength & dosage form	Bisolvon 0,2 % Solution, 10 mg per 5 mL solution
Variation classification & codes	Compliant response to CCR, dated 17/03/2022
Date of this submission	22 March 2022

Approved Patient Information Leaflet for BISOLVON® 0,2 % solution (Clean Copy)

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

BISOLVON® 0,2 % solution

Bromhexine hydrochloride

Sugar free.

Read all of this leaflet carefully because it contains important information for you.

BISOLVON 0,2 % solution is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use BISOLVON 0,2 % solution carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- 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 after 5 days.

What is in this leaflet

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1. What BISOLVON 0,2 % solution is and what it is used for

Bromhexine belongs to a group of medicines called secretolytic (medicines that help dissolve mucus or phlegm).

BISOLVON 0,2 % solution is used to relieve the symptoms of cough accompanied by excessive or thickened mucus (phlegm).

2. What you need to know before you take BISOLVON 0,2 % solution

Do not take BISOLVON 0,2 % solution

- if you are hypersensitive (allergic) to bromhexine or any of the other ingredients of BISOLVON 0,2 % solution (listed in section 6).

Warnings and precautions

Take special care with BISOLVON 0,2 % solution:

- if you have liver or kidney problems
- If you have problems with your lungs
- if you suffer from asthma
- If you have a history of, or existing, peptic ulceration.

If you are battling to breathe or are breathless, you should consult a doctor immediately.

If you are coughing up phlegm that is green or brown; or pink and foamy or contains blood you should consult a doctor immediately.

BISOLVON 0,2 % solution must not be given to children under 2 years except under medical supervision.

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Other medicines and BISOLVON 0,2 % solution

Ask your health care provider for advice before taking BISOLVON 0,2 % solution together with cough suppressants (medicines to stop a cough).

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

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 other health care provider for advice before taking this medicine.

It is preferable to avoid the use of BISOLVON 0,2 % solution during pregnancy.

BISOLVON 0,2 % solution should not be used during breastfeeding.

Driving and using machines

BISOLVON 0,2 % solution may cause dizziness. If you experience dizziness, you should not drive and use of machines.

BISOLVON 0,2 % solution contains methyl parahydroxybenzoate

BISOLVON 0,2 % solution contains 0,1 g of the excipient methyl parahydroxybenzoate in each 5 mL of oral solution, which may cause allergic reactions (possibly delayed).

3. How to take BISOLVON 0,2 % solution

Always take BISOLVON 0,2 % solution exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

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If you have the impression that BISOLVON 0,2 % solution is too strong or too weak, talk to your doctor or pharmacist.

Take BISOLVON 0,2 % solution as follows:

- Adults and children older than 10 years: Take 5 to 10 mL (one to two medicine measures) three times a day.
- Children under 10 years: Take 2,5 to 5 mL (one-half to one medicine measure) three times a day.

BISOLVON 0,2 % solution may also be administered by the inhaled route under medical supervision. Please contact your doctor or pharmacist for advice.

If you take more BISOLVON 0,2 % solution than you should

Overdosage could cause symptoms as mentioned under the section “Possible side effects”.
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take BISOLVON 0,2 % solution

If you miss a dose of this medicine, take it as soon as you remember. If it is nearly time for your next dose, skip the missed dose and go back to your usual dosing schedule. ***Do not double the dose.***

4. Possible side effects

BISOLVON 0,2 % solution can have side effects.
Not all side effects reported for BISOLVON 0,2 % solution are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking BISOLVON 0,2 %

solution, please consult your health care provider for advice.

If any of the following happens, stop taking BISOLVON 0,2 % solution and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing (dyspnoea).
- Rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to BISOLVON 0,2 % solution. You may need urgent medical attention or hospitalisation.

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

- A widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome), and a more severe form causing skin peeling covering a large area of your body (toxic epidermal necrolysis).
- Skin rash, which may form blisters and looks like small dark spots surrounded by a paler area, with a dark ring around the edge (erythema multiforme).
- Rapid appearance of areas of red skin studded with pinhead-sized sterile pustules on your face, your armpits or groin (acute generalised exanthematous pustulosis).
- Coughing, tightness in chest, wheezing, troubled breathing (bronchospasm).

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Nausea.
- Upper abdominal pain.

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- Vomiting.
- Diarrhoea.

Less frequent side effects:

- Fever.
- Headache.
- Dizziness.
- Sweating.

You may notice an expected increase in the flow of mucus as a result of taking BISOLVON 0,2 % solution.

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 or pharmacist. You can also report side effects to:

- The Pharmacovigilance Unit at Sanofi: za.drugsafety@sanofi.com (email) or 011 256 3700 (tel), or
- 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 BISOLVON® 0,2 % solution.

5. How to store BISOLVON 0,2 % solution

Store all medicines out of reach of children.

Store BISOLVON 0,2 % solution in a cool place (at or below 25 °C).

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

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Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What BISOLVON 0,2 % solution contains

The active substance is bromhexine hydrochloride.

Each 5 mL of solution contains 10 mg of bromhexine hydrochloride.

The solution is preserved with 0,1 % *m/v* methylparaben. The other ingredients are purified water and tartaric acid.

What BISOLVON 0,2 % solution looks like and contents of the pack

A clear, colourless liquid with a slightly bitter taste.

50 mL solution contained in amber-coloured glass bottles with tamper-evident closures.

Holder of the certificate of registration

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Midrand 1685

South Africa

Tel.: 011 256 3700

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Registration number

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