

**SCHEDULING STATUS:** **S0** **ACS RELIEF INHALER + ROLL ON – 2 IN 1 RELIEF. Inhaler: Each 0,5 ml contains:** Menthol (Mentha Sylvestris) 42 % w/v, Camphor (Cinnamomum Camphora) 41 % w/v, Wintergreen oil (Gaultheria Fragrantissima) 12,5 % w/v, Eucalyptus oil (Eucalyptus Globulus) 3 % w/v, Nutmeg Oil (Myristica fragrans) 1 % w/v. **Excipients:** Light Liquid Paraffin 0,5 % w/v. **Roll on- Each 1,0 ml contains:** Menthol (Mentha Sylvestris) 15 % w/w, Camphor (Cinnamomum Camphora) 15 % w/w, Eucalyptus oil (Eucalyptus Globulus) 4,5 % w/w, Wintergreen oil (Gaultheria Procumbens) 29,5 % w/w, **Excipients:** Light Liquid Paraffin 35 % w/w, Fragrance and Lavender 1 % w/w.

**Complementary Medicine: Discipline:** Aryuveda. This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use. Read all of this leaflet carefully because it contains important information for you. **ACS Relief Inhaler + Roll On** is available without a doctor's prescription and may assist you for the treatment of nasal congestion, headache, body ache, muscle strain or sprains and tension headaches. Nevertheless, you still need to use carefully to get the best results from it. Keep this leaflet. You may need to read it again. Do not share ACS Relief Inhaler + Roll On 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 after 7 days.

**What is in this leaflet. 1.** What ACS Relief Inhaler + Roll On is and what it is used for. **2.** What you need to know before you take ACS Relief Inhaler + Roll On. **3.** How to take ACS Relief Inhaler + Roll On. **4.** Possible side effects. **5.** How to store ACS Relief Inhaler + Roll On. **6.** Contents of the pack and other information.

**1. What ACS Relief Inhaler + Roll On is and what it is used for:** ACS Relief Inhaler + Roll On may assist with the relief for nasal congestion, headache, body ache, muscle strain or sprains and tension headaches. The formulae contains only herbal oils as active ingredients.

**2. What you need to know before you take ACS Relief Inhaler + Roll on:** Do not take ACS Relief Inhaler + Roll On if you are hypersensitive (allergic) to any of the ingredients. **Warnings and precautions:** Special care should be taken with ACS Relief and Roll On.

**Children and adolescents:** ACS Relief Inhaler and Roll On should only be used by Children over the age of 3 years or as directed by your doctor. Other medicines and ACS Relief Inhaler + Roll On. Always tell your health care provider if you are taking any other medicine. This includes all Complementary or Traditional medicines. No research has been done and no interactions are known to date.

ACS Relief Inhaler + Roll on with food, drink or alcohol. No known interactions have been recorded with concomitant use with alcohol.

**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 this medicine. **Driving and using machines:** It is not always possible to predict to what extent this product may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which ACS Relief Inhaler + Roll On affects them.

**3. How to take ACS Relief Inhaler + Roll On.** Do not share medicines prescribed for you with any other person. Always take the product as described in this leaflet or as your, doctor, pharmacist or nurse told you. Check with your doctor, or pharmacist, or nurse if you are not sure. The inhaler can be used as often as required to relieve a congested nose. Inhale the vapours through the nostril while keeping the other nostril closed. The Roll on oil can be used as often as needed to assist with headache, body ache, muscle strain or sprains and tension headaches. Apply on head temples or the side of the nose. **Method of administration. Inhaler:** Inhale the vapours through the nostril while keeping the other nostril closed. **Roll On:** Apply on head temples or the side of the nose. Please speak to your doctor or pharmacist if you feel the effect of the medicine is too strong or too weak. **If you take more ACS Relief Inhaler + Roll on more than you should:** In the event of overdose, ingestion consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. **If you forget to take ACS Relief Inhaler + Roll on.** Do not take / receive a double dose to make up for forgotten individual doses. Continue as per the instructions of a healthcare professional or in this leaflet.

**4. Possible side effects:** ACS Relief Inhaler + Roll on can have side effects. Not all side effects reported are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this product, please consult your health care provider for advice. If any of the following happens, stop using ACS Relief Inhaler + Roll on 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, rash or itching, fainting. • chest pain, angina, changes in the way your heart beats, for example, if you notice it beating faster, difficulty breathing, signs of recurrent infections such as fever or sore throat, less urine than is normal for you, yellowing of the skin and eyes, dark urine, and tiredness which may be symptoms of liver problems. These are all very serious side effects. If you have them, you may have had a serious reaction to the product. You may need urgent medical attention or hospitalisation. **Common/Frequent side effects:** • nausea (feeling sick), abdominal cramps or stomach pains, headache, dizziness, tiredness, light-headedness. **Uncommon/Less frequent side effects:** • dry cough, muscle cramps, flatulence or wind, diarrhoea, loss of appetite. 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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of ACS Relief Inhaler + Roll on.

**5. How to store ACS Relief Inhaler + Roll on:** Store all medicines out of reach of children. Store in a cool, dry place away from direct sunlight. Do not refrigerate, Store in the original package / container. Keep the container in the outer carton, Keep the container tightly closed, there are no special storage instructions for the product. Do not use after the expiry date stated on the label. 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 ACS Relief Inhaler + Roll on contains:** The active substances are all natural oils in a novel dosage form that contains both an inhaler and Roll on balm. **What ACS Relief Inhaler + Roll on looks like and contents of the pack.** Each pack contains a unit with an inhaler on one end and a roll on balm applicator on the other.

**Holder of Certificate of Registration:** Arya Pharma (Pty) Ltd, 417 Southern Klipriviersberg Road, Electron, Gauteng, 2192.

**This leaflet was last revised in June 2024.**

**Application number:** To be allocated