Avalon Pharma

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again
- If you have any further questions, ask your doctor or pharmacist.
- Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist. See section 4.

- 1. What AvalonActiv Extra Strength Cream is and what it is used for
- 2. Before you use AvalonActiv Extra Strength Cream.
- 3. How to use AvalonActiv Extra Strength Cream. 4. Possible side effects
- 5. How to store AvalonActiv Extra Strength Cream.
- 6. Further information

1. What AvalonActiv Extra Strength Cream is and what it is used for

AvalonActiv Extra Strength Cream is a non-greasy, pain reliving cream to applied to the skin. It is used for temporary relief of muscle and joint pain.

2. Before you use AvalonActiv Extra Strength Cream

Do not take AvalonActiv Extra Strength Cream if you have an allergy:

. to any of the ingredients of this product (listed in section 6). • to painkillers such as aspirin, ibuprofen and other non-steroidal anti-inflammatory drugs (NSAIDs)

Do not use AvalonActiv Extra Strength Cream on:

- · Children under 5 years of age
- . Your eyes or other sensitive areas. If this occurs accidentally wash away with plenty of clean water
- · Broken or inflamed skin

AvalonActiv Extra Strength Cream is only for use on the skin. Do not take by mouth.

Take special care with AvalonActiv Extra Strength Cream

See your doctor before using AvalonActiv Extra Strength Cream if you:

- · are pregnant or breastfeeding
- · have asthma. Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medcines, including products obtained without a prescription.

See your doctor before using AvalonActiv Extra Strength Cream if you are taking . Medicines that thin the blood or prevent clots (including aspirin).

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, ask your doctor or pharmacist for advice before taking this medicine

Important information about some of the ingredients of AvalonActiv Extra Strength Cream

AvalonActiv Extra Strength Cream contains:

Propylene glycol which may cause skin irritation

Lanoline anhydrous and cetostearyl alcohol which may cause local skin reactions (e.g. contact dermatitis)

If irritation occurs, stop using the cream and speak to your doctor or pharmacist

3. How to use AvalonActiv Extra Strength Cream

Always use AvalonActiv Extra Strength Cream exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

AvalonActiv Extra Strength Cream is for adults and children over 5 years old. It can be used before or after exercise

- · Always try on a small area first.
- . Gently massage a thin layer of AvalonActiv Extra Strength Cream to the affected area until the cream is rubbed in
- · Apply AvalonActiv Extra Strength Cream 2-3 times daily.
- Always wash your hands immediately after use so that you do not transfer it to sensitive areas such as your lips or eyes. If this occurs, wash away with plenty of clean water.
- · If your symptoms do not improve see your doctor
- Stop using AvalonActiv Extra Strength Cream if you get excessive skin irritation or other unwanted effects

Do not cover the skin with bandages, plasters or any other dressing. However, it is safe to cover the skin with your clothes.

If you use more AvalonActiv Extra Strength Cream than you should

If you accidently squeeze out too much cream use a tissue to wipe off any excess.

If you or a child accidentally swallow the cream contact your doctor or hospital immediately.

If you forget to use AvalonActiv Extra Strength Cream

If you forget to use the cream apply AvalonActiv Extra Strength Cream again when you remember. Do not use the cream more than 3 times in one day.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

AvalonActiv Extra Strength Cream

Menthol 5.91%, Eucalyptus Oil 1.97%,

Methyl Salicylate 12.80% and Turpentine Oil 1.47% w/w

4. Possible side effects

Like all products AvalonActiv Extra Strength Cream can cause side effects, although not everybody gets them.

The following effects may occur, particularly if you have sensitive skin or if you use Avalon-

- Activ Extra Strength Cream in hot weather or after a hot bath:
- . Temporary skin redness
- Burning sensation • Rashes

· Skin hurns or blisters

If you experience excessive skin irritation or any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store AvalonActiv Extra Strength Cream

- . Keep this medicine out of the sight and reach of children.
- Store below 30°C.
- . Shelf life after first opening is 8 months.
- . Do not use AvalonActiv Extra Strength Cream after the expiry date which is stated on the label and carton. The expiry date refers to the last day of that month.
- . Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines if you no longer use. These measures will help to protect the environment

6. Further information

What AvalonActiv Extra Strength Cream contains

- The active substances are:
- Menthol 5 91% w/w
- Eucalyptus Oil 1.97% w/w
- · Methyl Salicylate 12.80% w/w · Turpentine Oil 1.47% w/w

The other ingredients are: propylene glycol, benzyl alcohol, cetostearyl alcohol, paraffin oil, lanoline anhydrous, methyl paraben, propyl paraben, sodium cetostearyl sulfate and purified water

What AvalonActiv Extra Strength Cream looks like and contents of the pack AvalonActiv Extra Strength Cream is a white to off white cream.

Each tube contains 50 ml or 100 ml.

Manufacturer & Marketing Authorisation Holder:

Middle East Pharmaceutical Industries Co Ltd (Avalon Pharma)

P.O.Box 4180 Riyadh 11491

2nd Industrial City, Riyadh, Kingdom of Saudi Arabia

Tel: +966 (11) 2653948 -2653427 Fax: +966 (11) 2654723

This leaflet was approved in [01/2021]

To report any side effect(s):

· Saudi Arabia:

The National Pharmacovigilance and Drug Safety Centre (NPC)

- Fax: +966-11-205-7662
- SFDA call center: 19999
- Toll free phone: 8002490000
- E-mail: npc.drug@sfda.gov.sa Website: https://ade.sfda.gov.sa

Other GCC States:

Please contact the relevant competent authority.

THIS IS A MEDICAMENT

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor - Keep all medicaments out of reach of childre

Council of Arab Health Ministers, Union of Arab Pharmacists