

## Package leaflet: information for the user

# ANDROPATCH® 5 mg / 24 hours Transdermal Patch Testosterone

**Read all of this leaflet carefully before you start using this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms 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.

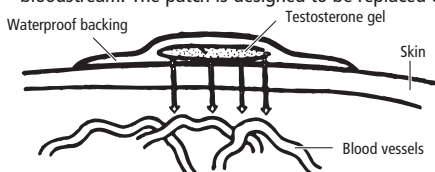
### In this leaflet:

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

## 1 What Andropatch is and what it is used for

Andropatch contains a medicine called testosterone.

- The testosterone in the patch is the same as natural testosterone produced by the testicles.
- The patch slowly releases testosterone into your skin. The testosterone passes through your skin and into your bloodstream. The patch is designed to be replaced each day.



Andropatch is used to replace testosterone in men who have low or no natural testosterone (called hypogonadism). This may be caused by:

- damage to the testicles (primary hypogonadism)
- damage to the parts of the brain which control the release of testosterone in the body (secondary hypogonadism).

Testosterone helps the penis and testicles to develop normally. It allows men to produce sperm and keep their sex drive. They also need testosterone to grow body hair and to develop their bones and muscles. It also makes their voice deepen.

Signs of low testosterone may include the following:

- Impotence (inability to get or keep an erection) and loss of sex drive
- Feeling tired with loss of energy
- Feeling depressed (low mood).

## 2 Before you use Andropatch

Do not use Andropatch if:

- You are allergic (hypersensitive) to testosterone or any of the other ingredients of Andropatch (See section 6: Further information)
- You are a woman
- You are under 15 years of age
- You have prostate cancer or an enlarged prostate gland
- You have male breast cancer
- You have a kidney problem called nephrotic syndrome
- You have high calcium levels in your blood or water (urine).

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before using Andropatch.

### Take special care with Andropatch

Before you use Andropatch, tell your doctor or pharmacist if:

- You have bone cancer
- You have any skin problems
- You have high blood pressure
- You have kidney, liver or heart problems
- You have migraines or epilepsy (fits)
- You have diabetes as your blood sugar levels may be affected. If you take insulin, your dose may need to be adjusted.

If you are elderly the doctor may discuss with you the effect of testosterone on your prostate. You may need regular checks of your prostate.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before using Andropatch. Even so your doctor may still want you to use Andropatch and will advise you about your medicine.

### Taking other medicines

Please tell your doctor or pharmacist if you are taking, or have recently taken any other medicines, including medicines obtained without a prescription. This includes herbal medicines. This is because Andropatch can affect the way some medicines work. Also some medicines can affect the way Andropatch works.

In particular tell your doctor or pharmacist if you are taking any of the following:

- Medicines that thin your blood (called anti-coagulants, such as warfarin). Andropatch can increase their blood thinning effect. Your blood results will need close monitoring, especially when starting or stopping your patches.
- Oxyphenbutazone (used in some eye ointments and to treat pains in your joints). Andropatch can raise the amount of oxyphenbutazone in your blood.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before using Andropatch.

### Pregnancy and breast-feeding

You must not use Andropatch if you are a woman.

It has not been tested in women and if you are pregnant, it may be harmful to unborn babies.

Do not breast-feed while using Andropatch.

## 3 How to use Andropatch

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

### Using this medicine

The usual starting dose is one patch each night. Look at the label on the pack to see how many patches your doctor would like you to use each day.

- Each patch should be **left on for approximately 24 hours**. Most patients use the 5 mg patch, and change it every 24 hours. If you need a higher or lower dose your doctor will tell you. Some patients need 2.5 mg every 24 hours and some patients need 7.5 mg every 24 hours.
- **Do not use more patches than your doctor has told you to use.** Your doctor will decide how long you need this treatment. Always follow your doctor's advice.
- You should stick each patch on at about **10 o'clock at night**. Do not worry if it is a little earlier or later.
- If you put your patch on at about 10 o'clock at night, your testosterone levels should change through the day, in the same way as natural testosterone.

### How to apply a patch

#### 1 Decide where you are going to put the patch

You can put the patch on your back, stomach, upper arms or thighs.

- Do not put Andropatch on bony areas. This includes your shoulders or hips, or on any part of your body that you may press on for a long time (such as when you are sleeping or sitting). Sometimes Andropatch may cause burn-like blisters if it is put on these parts of the body (See section 4: Possible side effects).
- Do not put the patch on broken or damaged skin.
- Do not put the patch on your scrotum (the sac which holds the testicles).

Some people prefer to choose an area of their body that will be covered by their clothes.

#### 2 Make sure the area you have chosen is clean and dry

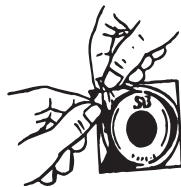
- The patch will stick better if the area is clean and dry.
- Do not put the patch on oily, damaged or sore skin.
- Avoid hairy areas if possible.

#### 3 Open the protective pouch

- Tear along the edge of the pouch and take out the patch.
- Once you have removed the patch, use it straight away.
- Do not store it once it is removed.

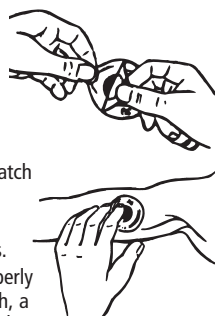
#### 4 Remove the backing

- Hold the tabs on the patch and gently peel off the backing.
- Throw the backing away.
- The backing is the half with the flat silver circle in the centre.



#### 5 Put the patch in place

- Place the patch on your skin and press firmly around the edges to make sure the patch sticks well.
- The patch should lie flat against your skin so the testosterone can get into your blood.
- If you are using more than one patch each day make sure they do not touch each other.
- Leave each patch on for 24 hours.
- If you have put the patch on properly you should be able to have a bath, a shower or go swimming without the patch coming off.



#### 6 Removing your patch

- When you have removed the patch, fold it in half with the sticky side inwards.
- Then put it in your household bin.
- A used patch will still contain some testosterone. The amount of gel left may vary from patch to patch.

**If you use more Andropatch than you should**

If you put on too many patches by mistake, take off the extra ones as soon as you realise. Do not put these extra patches back in their pouches. Get rid of them as outlined above (See point 6: Removing your patch).

**If you forget to use Andropatch**

- If it is before midday when you remember, put on or change the patch straight away. Then replace this new patch at about 10 o'clock at night as normal.
- If it is after midday when you remember, wait until the next patch should go on (about 10 o'clock at night), and change the patch as normal.
- Do not use a double dose to make up for a forgotten Andropatch.

**If the patch comes loose or falls off**

- If you do a lot of exercise or you sweat a lot, the patch may come loose or fall off.
- If the patch comes loose, smooth it down by pressing with your fingers around the edge of the patch.
- If the patch falls off before midday replace it with a new patch on the **same** place on your skin.
- If the patch falls off later in the day do not replace it until 10 o'clock that night, when you should be replacing it anyway. Put this new patch on a different area of your skin.

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

**4 Possible side effects**

Like all medicines, Andropatch can cause side effects, although not everybody gets them. The following side effects may happen with this medicine.

**Skin Problems**

Most patients get some redness, itching, burning, hardness or rashes on their skin where the patch has been at some time during their treatment. This usually disappears within 10 days of removing the patch. If the redness and itching are a particular problem, your pharmacist or doctor may be able to recommend a cream which will help. You can avoid or reduce these problems by putting your patch in a different place each day.

- Do not put a patch in the same place twice in the same week.
- Make sure that the patch is not put on broken or damaged skin, bony areas, such as your shoulders or hips, or on any part of the body that you may press on for a long time, for example when you are sleeping or sitting.

Sometimes a more severe skin reaction can occur causing a blister like a burn where the patch has been. **If this happens remove the patch straight away and tell your doctor as soon as possible.** The blisters may produce sores that take a few weeks to heal and may leave a scar.

**Tell your doctor if you notice any of the following:**

- an increase or decrease in the number of times you need to pass water
- the flow of your water stopping and starting whilst you are passing urine
- blood in your water
- your skin or the whites of your eyes turning yellow
- your water becomes darker and your faeces (poo) become paler.

Other side effects caused by testosterone include:

- headache
- an increase in blood pressure
- feeling depressed (low mood) or anxiety
- blood in your faeces (poo)
- possible changes in your prostate gland
- increased body hair or baldness
- oily skin or acne
- feeling sick (nausea)

- swollen ankles, muscle weakness or pins and needles
- frequent or long lasting erections
- increases or decreases in your sex drive.

Men having testosterone have also sometimes had:

- low sperm counts, with high doses, or
- changes in the levels of salts in their bodies, if used for a long time. Symptoms may include tiredness, confusion, swollen hands or feet, muscle weakness or twitching, or abnormal heart beat.

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.

**5 How to store Andropatch**

- Keep out of the reach and sight of children.
- Do not use Andropatch after the expiry date on the carton and the pouch. The expiry date refers to the last day of the month.
- Do not store above 25°C.
- Apply to skin immediately upon removal from the protective pouch. Store in the original package.
- Do not use Andropatch if the patches are damaged.
- Ask your pharmacist how to dispose of medicines no longer required. Used patches can be placed in your household waste. (See section 3: How to use Andropatch)

**6 Further information**

**What Andropatch 5 mg contains**

- The active substance is testosterone.
- The testosterone is in a gel.
- Each Andropatch 5 mg patch contains 24.3 milligrammes (mg) of testosterone.
- The patch delivers a total of 5 mg of testosterone each day.
- This is delivered through the skin over a surface area of 15 cm<sup>2</sup>.

The other ingredients are ethanol, purified water, glycerol (E422), glycerol mono-oleate, methyl laurate, carbomer copolymer B and sodium hydroxide (E524).

**What Andropatch 5 mg looks like and contents of the pack**

Andropatch 5 mg is an oval, beige, patch. Each patch comes in a protective pouch. Andropatch 5 mg is available in packs of 30 transdermal patches.

Components of the patch: silicone-coated polyester liner, acrylic adhesive/silicone-coated PET laminate, peelable LDPE/aluminium/polyester film, microporous HMWPE (high molecular weight polyethylene) film. Backing film: inner layer of EVA, Surlyn® and metallised polyethylene. Outer layer: polyethylene layer, pigmented with alcohol resistant beige ink to form a beige, plastic film.

**Marketing Authorisation Holder and Manufacturer**

Marketing Authorisation Holder: SmithKline Beecham plc, trading as GlaxoSmithKline UK, Stockley Park West, Uxbridge, Middlesex, UB11 1BT, UK.

Manufacturer: SmithKline Beecham Pharmaceuticals, Magpie Wood, Manor Royal, Crawley, West Sussex, UK.

**Other formats:**

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge: 0800 198 5000 (UK Only)

Please be ready to give the following information:

**Product Name    Andropatch 5 mg**

Reference number 10592/0106

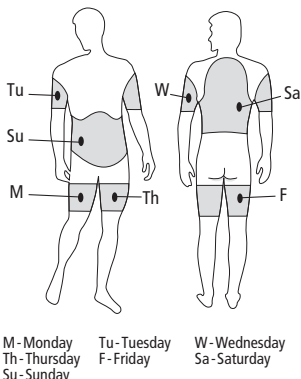
This is a service provided by the Royal National Institute of the Blind.

**Patient reminder chart**

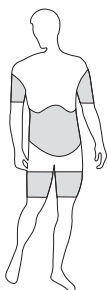
Make sure you change the position of your patches each day. **Do not put a patch in the same place on your body twice in the same week.** This chart can be used to help you remember where you have put your patches each day.

You can put Andropatch on your back, stomach, upper arms or thighs.

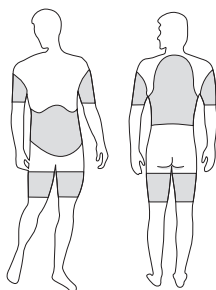
**Example**



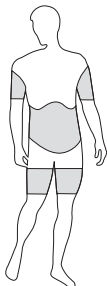
**Week 1  
Dates**



**Week 2  
Dates**



**Week 3  
Dates**



**Week 4  
Dates**

