Package leaflet: information for the user Anquil 0.25 mg tablets

benperidol

Please read all of this leaflet carefully before you start taking 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.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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1. What Anguil 0.25 mg tablets are and what they are used for

Anquil tablets contain the active ingredient benperidol which belongs to a group of medicines called antipsychotics. Anquil tablets are used to treat anti-social sexual behaviour which may cause offence to others.

2. What you need to know before you take Anguil 0.25 mg tablets

Do not take Anquil

- if you are allergic to benperidol or any of the other ingredients or to other antipsychotics (see section 6 and also end of section 2)
- have reduced awareness or your reactions are slower, either because you are taking other medicines, or for any other reason
- have Parkinson's disease
- suffer from depression
- have movement problems such as twitching, muscle stiffness, trembling or restlessness.

If any of these apply to you, tell your doctor.

Warnings and precautions

Talk to your doctor before taking Anquil. If you have any of the following conditions you may need to be monitored closely during treatment and the dose may have to be altered:

- heart or blood vessel disease (either you or anyone in your family)
- history of blood clots (either you or anyone in your family), as medicines like these have been associated with the formation of blood clots.
- low levels of potassium, calcium or magnesium in your blood
- liver or kidney disease
- epilepsy or any other condition that can cause convulsions (fits)
- risk factors for stroke, such as:
 - a family history of strokes
 - certain medical conditions including: abnormalities in the blood vessels, abnormal cholesterol level, diabetes, hardening of the arteries, high blood pressure, obesity or transient ischaemic attacks (mini strokes)

• smoking, a diet high in salt and fats, lack of physical activity or substance or alcohol misuse.

Smoking and drinking alcohol may cause the tablets to be less effective.

If you need to take Anquil for a long time, your doctor may want to carry out regular blood tests.

Other medicines and Anquil

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

The dose of Anquil may need to be increased, reduced or stopped altogether if you are taking certain medicines. Tell your doctor if you are already taking any of the following:

- medicines to calm you down or help you to sleep (sedatives or hypnotics) including buspirone, strong painkillers, some allergy medications (antihistamines, such as chlorphenamine) and certain antidepressants such as fluoxetine and lithium
- adrenaline and other medicines which work in a similar way
- medicines to lower blood pressure, including methyldopa
- medicines to treat Parkinson's disease, including, levodopa, pramipexole and ropinirole
- medicines to treat epilepsy, including phenobarbital, carbamazepine, phenytoin, rifampicin, primidone, oxcarbazepine, ethosuximide and valproate
- medicines that affect the rhythm of the heart, such as amiodarone and moxifloxacin
- ritonavir (an antiviral drug), artemether and lumefantrine (for malaria), amantadine (for nervous system disorders), metoclopramide (for nausea/vomiting), tetrabenazine (for movement disorders), memantine (for Alzheimer's disease), sodium benzoate (a preservative) or sodium phenylbutyrate (for metabolic disorders).

Anguil with food, drink and alcohol

You should avoid drinking alcohol as the combined effect of Anquil and alcohol might make you feel drowsy. Drinking alcohol may also cause the tablets to be less effective. Anquil can be taken with or without food.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. Your doctor will decide if you can take these tablets.

The following symptoms may occur in newborn babies, of mothers that have used Anquil in the last trimester (last three months of their pregnancy): shaking, muscle stiffness and/or weakness, sleepiness, agitation, breathing problems, and difficulty in feeding. If your baby develops any of these symptoms you may need to contact your doctor.

Do not breast-feed if you are taking Anguil.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Anquil tablets might make you drowsy or sleepy. Do not drive or operate machinery until you know if the tablets affect you.

Anquil contains lactose

Lactose is one of the ingredients in this product. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking these tablets.

3. How to take Anguil 0.25 mg tablets

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will tell you how many tablets to take and for how long you should take them.

Swallow the tablets with some water. You can take them with or without food.

Adults

The dose will vary from person to person and your doctor will adjust the number of tablets to suit you. This will be between one and six tablets per day. It is very important that you take the correct amount.

Use in the elderly, adolescents or frail persons

Young adults, the elderly or frail persons may require a lower dose. Your doctor will tell you how many tablets to take if this applies to you.

Children

Anguil tablets are not recommended for use in children.

Important – it may take some time before you feel the full effect of the tablets but it is important that you carry on taking them for as long as your doctor has told you to.

If you take more Anguil than you should

If you take more tablets than you were told to, contact your doctor straight away or contact the nearest hospital accident and emergency department immediately. Take this leaflet and the pack of Anquil along with you, if you can.

If you forget to take Anguil

If you forget to take your tablets, take your next dose the next day at the usual time and continue taking the tablets according to your doctor's instructions. Do not take a double dose to make up for a forgotten dose. If in doubt about what you should do, please contact your doctor.

If you stop taking Anquil

If you stop taking Anquil, you should do so gradually, especially if you have been taking a high dose, unless your doctor has told you otherwise. Stopping treatment suddenly may cause effects such as feeling sick, vomiting or sleeplessness. Always follow your doctor's instructions carefully.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking Anquil and tell your doctor immediately if you experience any of the following symptoms:

- sweating and an increased heart rate as it may lead to fever, muscle stiffness, faster breathing and reduced consciousness
- swelling, pain and redness, especially of the leg which may indicate blood clots in the veins. Blood clots can travel through blood vessels to the lungs, causing chest pain and difficulty in breathing.
- abnormal tongue movements as it may lead to additional movement problems such as twitching, muscle stiffness, muscle spasms, throat spasms, a slowing of movements, trembling and restlessness
- twitching or abnormal movements of the face, mouth, jaw or throat, or rolling of the eyes may also occur
- convulsions (fits)
- jaundice (yellowing of the skin or whites of the eyes)
- fever

You may experience any of these symptoms while you are taking Anquil or when you stop taking the tablets. In some patients, these symptoms may be permanent.

Other side effects include:

Uncommon (affects less than 1 in 100 people)

• a slight fall in blood pressure causing you to feel lightheaded (particularly in the elderly)

Rare (affects less than 1 in 1,000 people)

- depression
- feelings of confusion
- excitement and agitation
- an increase in the speed of your heartbeat

The following side effects have also been reported (frequency not known)

- women may suffer from inappropriate milk secretion, an absence of their monthly period or changes in the regularity of their periods
- men may experience some swelling of the breasts
- weight change
- dizziness
- headache
- tiredness, sleepiness or reduced alertness
- difficulty in sleeping
- loss of appetite
- feeling sick, vomiting, constipation or indigestion
- increased salivation
- skin rashes, itching or swelling
- allergic skin reactions
- mouth ulcer
- infections

In elderly people with dementia, a small increase in the number of deaths has been reported for patients taking antipsychotics compared with those not receiving antipsychotics.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme. Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Anguil 0.25 mg tablets

Keep this medicine out of the sight and reach of children.

Store below 25°C. Keep in the original pack in order to protect from light.

Do not use this medicine after the expiry date which is stated on the carton after 'Expiry:' The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Anquil 0.25 mg tablets contain

The active substance is benperidol (0.25 mg).

The other ingredients are:

- lactose (see section 2 "Anquil contains lactose"))
- starch
- magnesium stearate.

What Anguil 0.25 mg tablets look like and contents of the pack

White tablets, marked with "025" on one side and a breakline line on the other. The tablets are supplied in blister packs containing 100 or 112 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Neon Healthcare Limited Mill Studio Business Centre Crane Mead Ware Hertfordshire SG12 9PY UK

Manufacturer

Dales Pharmaceuticals Ltd Snaygill Industrial Estate Keighley Road Skipton North Yorkshire BD23 2RW UK

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