Package leaflet: Information for the user

D06627

Ambinet XL 5, 10, 20, 30, 40, 50, 60 mg modified-release hard capsules

methylphenidate hydrochloride

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 only. 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

1. What Ambinet XL is and what it is used for
2. What you need to know before you or your child takes Ambinet XL
3. How to take Ambinet XL
4. Possible side effects
5. How to store Ambinet XL
6. Contents of the pack and other information

1. What Ambinet XL is and what it is used for

What is used for
Ambinet XL is used to treat 'attention deficit hyperactivity disorder' (ADHD).
- it is used in children aged 6 years and over and in adults.
- it is used only after treatments have been tried which do not involve medication e.g. counselling and behavioural therapy and which have been insufficient.

Ambinet XL is not for use as a treatment for ADHD in children under 6 years of age.

How it works
Ambinet XL improves the activity of certain parts of the brain which are under-active. The medicine can help improve attention span and concentration, and reduce impulsive behaviour.

The medicine is given as part of a treatment programme, which usually includes
- psychological,
- educational and
- social therapy.

Ambinet XL treatment must only be initiated by, and used under the supervision of a doctor, specialised in the treatment of ADHD, such as an expert paediatrician, a child and adolescent psychiatrist or a psychiatrist. A careful examination by this doctor is required. If you as an adult have not been treated before, the doctor will perform tests to confirm that you have been affected by ADHD since childhood. Although there is no cure for ADHD, it can be managed using treatment programmes.

About ADHD
Children and young people with ADHD find it:
- hard to sit still and
- hard to concentrate.

It is not their fault they cannot do these things.

Patients can have ADHD in varying degrees with symptoms including:
- lack of concentration
- restlessness
- hyperactivity
- impulsivity
- emotional instability
- disorganised thinking

This is shown by, for example:
- difficulty concentrating
- forgetfulness
- talking too much
- difficulties in planning and carrying out tasks to completion
- "blindfold actions"
- impatience

ADHD does not affect the intelligence of a child or young person.

2. What you need to know before you or your child takes Ambinet XL

Do not take Ambinet XL if you or your child
- is allergic to methylphenidate or any of the other ingredients of this medicine (listed in section 6)
- has a thyroid problem
- has increased pressure in the eye (glaucoma)
- has a tumour of the adrenal gland (phaeochromocytoma)
- has an eating problem when you do not feel hungry or want to eat - such as 'anorexia nervosa'
- has very high blood pressure or narrowing of the blood vessels, which can cause pain in the arms and legs
- has ever had heart problems - such as a heart attack, uneven heartbeat, pain and discomfort in the chest, heart failure, heart disease or was born with a heart problem
- has had a problem with the blood vessels in the brain - such as a stroke, swelling and weakening of part of a blood vessel (aneurysm), narrow or blocked blood vessels, or inflammation of the blood vessels (vasculitis)
- is currently taking or has taken within the last 14 days an antidepressant (known as a monoamine oxidase inhibitor), see 'Other medicines and Ambinet XL'
- has mental health problems such as:
  - a 'psychopathic' or 'borderline personality' problem
  - abnormal thoughts or visions or an illness called 'schizophrenia'
  - signs of a severe mood problem like:
    - feeling like killing yourself
    - severe depression, where you feel very sad, worthless and hopeless
    - mania, where you feel unusually excitable, over-active, and un-inhibited.
- has a history of pronounced lack of gastric acid (anacidity of the stomach) with a pH value above 5.5
- is taking medicines to reduce secretion of gastric acid or to treat excessive acidity of the stomach (H2 receptor blocker, proton pump inhibitor or antacid treatment)

Do not take methylphenidate if any of the above apply to you or your child. If you are not sure, talk to your doctor or pharmacist before you or your child takes methylphenidate. This is because methylphenidate can make these problems worse.

Warnings and precautions
Talk to your doctor before taking Ambinet XL if you or your child
- has liver or kidney problems
- has problems with swallowing or swallowing whole tablets
- has had fits (seizures, convulsions, epilepsy) or any abnormal brain scans (EEGs)
- has ever abused or been dependent on alcohol, prescription medicines or street drugs
- is female and has started having periods (see the 'Pregnancy and breast-feeding' section below)
- has hard-to-control, repeated twitching of any parts of the body or repeats sounds and words (tics)
- has high blood pressure
- has a heart problem which is not in the 'Do not take' section above
- has a mental health problem which is not in the 'Do not take' section above. Other mental health problems include:
  - mood swings (from being manic to being depressed - called 'bipolar disorder')
  - starting to be aggressive or hostile, or aggression gets worse
  - seeing, hearing or feeling things that are not there (hallucinations)
  - believing things that are not true (delusions)
  - feeling unusually suspicious (paranoia)
  - feeling agitated, anxious or tense
  - feeling depressed or guilty

Tell your doctor or pharmacist if any of the above apply to you or your child before starting treatment. Methylphenidate can make these problems worse. Your doctor will want to monitor how the medicine affects you or your child.

If you or your child develop blurred vision or other visual disturbances contact your doctor. Your doctor may consider discontinuation of Ambinet XL.

During treatment, boys and adolescents may unexpectedly experience prolonged erections. This may be painful and can occur at any time. It is important to contact your doctor straight away if your erection lasts for longer than 2 hours, particularly if this is painful.

Checks that your doctor will make before you start taking methylphenidate
These checks are to decide if methylphenidate is the correct medicine for you or your child. Your doctor will talk to you about:
- any other medicines you or your child is taking
- whether there is any family history of sudden unexplained death
- any other medical problems (such as heart problems) you or your family may have
- how you or your child is feeling, such as feeling high or low, having strange thoughts and if you or your child has had any of these feelings in the past
- whether there is a family history of 'tics' (hard-to-control, repeated twitching of any parts of the body or repeating sounds and words)
- any mental health or behavioural problems you or your child or other family members have ever had.

Your doctor will discuss whether you or your child is at risk of having mood swings (from being manic to being depressed - called 'bipolar disorder'). They will check you or your child's mental health history, and check if any of your family have a history of suicide, bipolar disorder or depression.

It is important that you provide as much information as you can. This will help your doctor decide if methylphenidate is the correct medicine for you or your child. Your doctor may decide that other medical tests are needed before you or your child start taking this medicine. For adult patients that are new to Ambinet XL, your doctor may refer you to a heart specialist.

Drug testing
This medicine may give a positive result when testing for drug use.
Athletes must be aware that this medicinal product may cause a positive reaction to 'anti-doping' tests.

Other medicines and Ambinet XL
Please tell your doctor or pharmacist if you or your child is taking, has recently taken or may take any other medicines.

Do not take methylphenidate if you or your child:
- is taking a medicine called a 'monoamine oxidase inhibitor' (MAOI) used for depression, or has taken an MAOI in the last 14 days. Taking an MAOI with methylphenidate may cause a sudden increase in blood pressure.

If you or your child is taking other medicines, methylphenidate may affect how well they work or may cause side effects. Tell your doctor if you or your child is taking medicines to treat:
- depression
- mental health problems
- epilepsy
- blood pressure problems
- cough and colds. Some remedies contain medicines that can affect blood pressure. It is important to check with your pharmacist when you buy any of these products
- medicines that thin the blood to prevent blood clots

Ambinet XL must not be taken together with H2 receptor blockers, proton pump inhibitors or antacids which are used to reduce gastric acid secretion or to counteract excessive acidity in the stomach, as this could lead to a faster release of the total amount of active substance.

If you are in any doubt about whether any medicines you or your child is taking are included in the list above, ask your doctor or pharmacist for advice before taking methylphenidate.

Having an operation
Tell your doctor if you or your child is going to have an operation. Methylphenidate should not be taken on the day of surgery if a certain type of anaesthetic is used. This is because there is a chance of a sudden rise in blood pressure during the operation.

Taking methylphenidate with alcohol
Do not drink alcohol while taking this medicine. Alcohol may make the side effects of this medicine worse. Remember that some foods and medicines contain alcohol.

Pregnancy and breast-feeding
Available data do not suggest an increased risk of overall birth defects, whilst a small increase in the risk of malformations of the heart when used during the first three months of pregnancy could not be ruled out. Your doctor will be able to give you more information about this risk. Tell your doctor or pharmacist before using methylphenidate if you or your daughter:
- is having sex. Your doctor will discuss contraception.
- is pregnant or think she might be pregnant. Your doctor will decide whether methylphenidate should be taken.
- is breast-feeding or planning to breast-feed. It is possible that methylphenidate is passed into human breast milk. Therefore, your doctor will decide whether you or your daughter should breast-feed while taking methylphenidate.

Driving and using machines
You or your child may feel dizzy, feel drowsy, have problems focussing or have blurred vision, have hallucinations or other side effects in the central nervous system when taking methylphenidate. If these happen it may be dangerous to do things such as drive, use machines, ride a bike or horse or climb trees.

3. How to take Ambinet XL

You or your child should always take Ambinet XL exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Dosage
Use in children
The maximum daily dose is 60 mg.
- your doctor will usually start treatment with a low dose and increase it gradually as required.
- your doctor will tell you what strength of capsule to take each day.
- do not split the dose of a capsule; take the entire contents.
- Ambinet XL should not be taken too late in the morning as it may cause disturbances in sleep.

Use in adults
For adults who have taken Ambinet XL before
- if you have already taken methylphenidate as a child or adolescent, the same daily dosage (mg/day) can be used; your doctor will check regularly to see if any adjustment is required.
- adult patients may require a higher daily dosage but the doctor will aim to give you the lowest dose that is effective.
- the maximum daily dose is based among other things on your body weight (see below).

For adults who have not taken Ambinet XL before
The recommended starting dose is 10 mg daily.
- your doctor will increase your dose in increments of 10 mg daily, depending on how well you tolerate the medicine and how effective it is.
- the aim should be the lowest dose that is effective for you.
- the maximum daily dose is based among other things on your body weight (see below).
- your doctor will decide the maximum daily dose for you.
- the daily dose is 1 mg per kg body weight, up to a maximum of 80 mg of methylphenidate daily.

Things your doctor will do when you or your child is undergoing treatment
Your doctor will do some tests
- before you or your child starts - to make sure that Ambinet XL safe and will be of benefit.
- after you or your child starts - they will be done at least every 6 months, but possibly more often they will also be done when the dose is changed.
- these tests will include:
  - checking appetite
  - measuring height and weight for children
  - measuring weight for adults
  - measuring blood pressure and heart rate
  - checking problems with mood, state of mind or any other unusual feelings. Or if these have got worse while taking Ambinet XL.

Method of administration
The medicinal product is intended for oral use.

Children take Ambinet XL in the morning with or after breakfast.
Adults take Ambinet XL with or after breakfast **and** lunch.

Ambinet XL is a form of methylphenidate with "controlled release" action, which releases the drug gradually over a prolonged period of time. Taking the capsule with or after meals is very important in order for their action to be delayed.

The capsules may be swallowed whole with a drink of water. Alternatively, you can open the capsules, sprinkle the contents onto a small amount (tablespoon) of applesauce or yoghurt and take it immediately. Do not store for future use. The capsules and the capsule contents must not be crushed or chewed.

If you or your child does not feel better after 1 month of treatment
If you or your child does not feel better after 1 month of treatment, tell your doctor. Your doctor may decide that you or your child needs a different treatment.

Long-term treatment
Ambinet XL does not need to be taken for ever. If you or your child takes Ambinet XL for more than a year, your doctor should stop treatment at least once per year for a short time. In case of children this may happen during a school holiday. This will show if the medicine is still needed.

Not using Ambinet XL properly
If Ambinet XL is not used properly, this may cause abnormal behaviour. It may also mean that you or your child starts to depend on the medicine. Tell your doctor if you or your child has ever abused or been dependent on alcohol, prescription medicines or street drugs.
This medicine is only for you. Do not give this medicine to anyone else, even if their symptoms seem similar.

If you or your child takes more Ambinet XL than you should
If you or your child takes too much of the medicine, talk to a doctor or call an ambulance straight away. Tell them how much has been taken. You may need medical treatment.

Signs of overdose may include: being sick, feeling agitated, shaking, increased uncontrolled movements, muscle twitching, fits (may be followed by coma), feeling very happy, being confused, seeing, feeling or hearing things that are not real (hallucinations), sweating, flushing, headache, high fever, changes in heart beat (slow, fast or uneven), high blood pressure, dilated pupils and dry nose and mouth, muscle spasms, fever and reddish-brown urine which could be possible signs of abnormal breakdown of muscles (rhabdomyolysis).

If you or your child forgets to take Ambinet XL
Do not take a double dose to make up for a forgotten dose. If you or your child forgets a dose, wait until it is time for the next dose.

If you or your child stops taking Ambinet XL
If you or your child suddenly stops taking this medicine, ADHD symptoms may come back or unwanted effects such as depression may appear. Your doctor may want to gradually reduce the amount of medicine taken each day, before stopping it completely. Talk to your doctor before stopping Ambinet XL.

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, but although not everybody gets them. Your doctor will talk to you about these side effects.

Some side effects could be serious. If you have any of the side effects below, see a doctor straight away:

Common (may affect up to 1 in 10 people)
- uneven heart beat (palpitations)
- changes in personality
- excessive teeth grinding (bruxism)

Uncommon (may affect up to 1 in 100 people)
- mood swings, mood changes
- thinking about or feeling like killing yourself
- seeing, feeling or hearing things that are not real - these are signs of psychosis
- uncontrolled speech and body movements (Tourette's) or worsening of it
- chest pain
- signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing

Rare (may affect up to 1 in 1 000 people)
- feeling unusually excited, over-active and un-inhibited (mania)

Very rare (may affect up to 1 in 10 000 people)
- heart attack
- fits (seizures, epilepsy with convulsions)
- skin peeling or purplish red patches
- muscle spasms which you cannot control affecting your eyes, head, neck, body and nervous system - due to a temporary lack of blood supply to the brain
- paralysis or problems with movement and vision, difficulties in speech (these can be signs of problems with the blood vessels in your brain), temporary lack of adequate blood and oxygen (ischemia) to the brain
- decrease in number of blood cells (red cells, white cells and platelets) which can make you more likely to get infections, and make you bleed and bruise more easily
- a sudden increase in body temperature, very high blood pressure and severe convulsions ('Neuroleptic Malignant Syndrome'). It is not certain whether this side effect is caused by methylphenidate or other drugs that may be taken in combination with methylphenidate

Not known (frequency cannot be estimated from available data)
- unwanted thoughts that keep coming back
- unexplained fainting, chest discomfort, shortness of breath (these can be signs of heart problems)

If you have any of the side effects above, see a doctor straight away.

Other side effects include the following, if they get serious, please tell your doctor or pharmacist:

Very common (may affect more than 1 in 10 people)
- decreased appetite
- headache
- feeling nervous
- not being able to sleep
- dry mouth
- being sick

Common (may affect more than 1 in 10 people)
- feeling depressed or lack of feeling or emotion or showing much interest
- joint pain
- high temperature (fever)
- unusual hair loss or thinning
- feeling unusually sleepy or drowsy
- loss of appetite
- panic attack
- reduced sex drive
- toothache
- itching, rash or raised red itchy rashes (hives)
- cough, sore throat or nose and throat irritation, shortness of breath or chest pain
- changes in blood pressure (usually high blood pressure)

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- fast heart beat (tachycardia), cold hands and feet
- shaking and trembling, feeling dizzy
- movements which you cannot control, feeling of inner restlessness
- being unusually active
- feeling aggressive, agitated, restless, emotional unstable, anxious, depressed, stressed, irritable and abnormal behaviour, problems sleeping, fatigue, somnolence
- stomach pain, diarrhoea, stomach discomfort, indigestion, thirst, vomiting. These usually occur at the beginning of treatment and may be reduced by taking the medicine with food
- lack of appetite/ not willing to eat
- weight loss
- excessive sweating

Uncommon (may affect up to 1 in 100 people)
- muscle pain, muscle twitching, muscle tightness
- constipation
- chest pain
- inflammation of the mucous membranes of stomach and small intestine
- extra sound during heart beat (based on investigation findings)
- blood in the urine
- double vision or blurred vision
- increases in liver test results (seen in a blood test)
- anger, feeling tearful, excessive awareness of surroundings, tension
- feeling very calm or sleepy
- problems with the sleep in general
- fatigue
- dry eye

Rare (may affect up to 1 in 1 000 people)
- changes in sex drive
- feeling disorientated
- dilated pupils, trouble seeing
- swelling of the breasts in men
- redness of the skin, red raised skin rash
- pain resulting from not enough blood flow to the heart
- problems/ changes in the menses
- obsessive-compulsive disorder (OCD) (including irresistible urge to pull out body hair, skin picking, having repeated unwanted thoughts, feelings, images or urges in your mind (obsessive thoughts), performing repeated behaviours or mental rituals (compulsions))

Very rare (may affect up to 1 in 10 000 people)
- heart attack
- sudden death
- muscle cramps
- small red marks on the skin
- inflammation or blocked arteries in the brain
- abnormal liver function including liver failure and coma
- changes in test results – including liver and blood tests
- suicidal attempt (including completed suicide), abnormal thinking, lack of feeling or emotion
- lack of energy
- feeling sad over a short period of time
- fingers and toes feeling numb and cold, tingling and changing colour (from white to blue, then red) when cold ('Raynaud's phenomenon')

Not known (frequency cannot be estimated from available data)
- migraine
- increased pressure in the eye
- eye diseases which may cause decreased vision due to damage to the eye nerve (glaucoma)
- very high fever
- slow, fast or extra heart beats
- a major fit ('grand mal convulsions')
- believing things that are not true
- confusion
- sad/ dark thoughts
- feeling a bodily need of the medication or feeling its absence
- problems with the blood vessels of the brain (stroke, cerebral arteritis or cerebral occlusion)
- erectile dysfunction
- prolonged erections, sometimes painful, or an increased number of erections
- excessive uncontrolled talking
- ADHD-symptoms may come back or unwanted effects such as depression may appear after stop of medication
- tingling sensation
- problems with language and speaking
- retching
- disturbance in attention
- influenza illness
- loss of energy/ feeling weak
- feeling thirsty
- increases in blood thyroid stimulating hormone levels
- pain in the area of mouth and throat
- nose bleeding
- heart discomfort
- higher pressure inside the eye than normal
- stress with partner/ family
- breast pain
- hot flush/ flushing
- ringing in the ears (tinnitus)
- abuse
- pancytopenia (abnormal decrease in the levels of all type of blood cells)
- inability to control the excretion of urine (incontinence)
- spasm of the jaw muscles that makes it difficult to open the mouth (trismus)
- stuttering

Effects on growth
When used for more than a year, methylphenidate may cause reduced growth in some children. This affects less than 1 in 10 children.
- there may be lack of weight gain or height. Your doctor will carefully watch you or your child's height and weight, and how well you or your child is eating.
- if you or your child is not growing as expected, then treatment with methylphenidate may be stopped for a short time.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions 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.

5. How to store Ambinet XL

Blisters: Do not store above 25 °C.

Bottle: Do not store above 30°C.

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

Do not use this medicine after the expiry date which is stated on the carton and the blister after {EXP}. 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 you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Ambinet XL contains
The active substance is methylphenidate hydrochloride.

Ambinet XL 5 mg modified-release hard capsules
Each modified-release hard capsule contains 5 mg methylphenidate hydrochloride as 4.325 mg methylphenidate.

Ambinet XL 10 mg modified-release hard capsules
Each modified-release hard capsule contains 10 mg methylphenidate hydrochloride as 8.65 mg methylphenidate.

Ambinet XL 20 mg modified-release hard capsules
Each modified-release hard capsule contains 20 mg methylphenidate hydrochloride as 17.3 mg methylphenidate.

Ambinet XL 30 mg modified-release hard capsules
Each modified-release hard capsule contains 30 mg methylphenidate hydrochloride as 25.95 mg methylphenidate.

Ambinet XL 40 mg modified-release hard capsules
Each modified-release hard capsule contains 40 mg methylphenidate hydrochloride as 34.6 mg methylphenidate.

Ambinet XL 50 mg modified-release hard capsules
Each modified-release hard capsule contains 50 mg methylphenidate hydrochloride as 43.25 mg methylphenidate.

Ambinet XL 60 mg modified-release hard capsules
Each modified-release hard capsule contains 60 mg methylphenidate hydrochloride as 51.9 mg methylphenidate.
The other excipients are:
Capsule contents: cellulose, microcrystalline, hypromellose, talc, hypromellose acetate succinate, hydroxypropyl cellulose, hydrochloric acid (for pH-adjustment).
Capsule shell: gelatin, titanium dioxide (E171), iron oxide yellow (E172) (additionally in Ambinet XL 10 mg, 30 mg, 40 mg and 60 mg modified-release hard capsules), iron oxide red (E172) (additionally in Ambinet XL 5 mg modified-release hard capsules)
Printing ink: shellac glaze (E904), iron oxide black (E172), propylene glycol (E1520), potassium hydroxide (E525) (in Ambinet XL 10 mg, 20 mg, 30 mg, 40 mg, 50 mg and 60 mg modified-release hard capsules), shellac glaze (E904), titanium dioxide (E171), propylene glycol (E1520) (additionally in Ambinet XL 5 mg modified-release hard capsules)

What Ambinet XL looks like and contents of the pack
Ambinet XL 5 mg modified-release hard capsules
Hard gelatin capsule with orange cap and orange body imprinted "5" with white ink on body filled with white to off-white spherical pellets. Capsule length: 14.3 mm, size 4.

Ambinet XL 10 mg modified-release hard capsules
Hard gelatin capsule with yellow cap and white body imprinted "10" with black ink on body filled with white to off-white spherical pellets. Capsule length: 14.3 mm, size 4.

Ambinet XL 20 mg modified-release hard capsules
Hard gelatin capsule with white cap and white body, imprinted "20" with black ink on body filled with white to off-white spherical pellets. Capsule length: 15.9 mm, size 3.

Ambinet XL 30 mg modified-release hard capsules
Hard gelatin capsule with ivory cap and ivory body, imprinted "30" with black ink on body filled with white to off-white spherical pellets. Capsule length: 18 mm, size 2.

Ambinet XL 40 mg modified-release hard capsules
Hard gelatin capsule with yellow cap and yellow body, imprinted "40" with black ink on body filled with white to off-white spherical pellets. Capsule length: 19.4 mm, size 1.

Ambinet XL 50 mg modified-release hard capsules
Hard gelatin capsule with white cap and white body imprinted "50" with black ink on body filled with white to off-white spherical pellets. Capsule length: 21.7 mm, size 0.

Ambinet XL 60 mg modified-release hard capsules
Hard gelatin capsule with ivory cap and white body imprinted "60" with black ink on body filled with white to off-white spherical pellets. Capsule length: 21.7 mm, size 0.

Pack sizes
Ambinet XL 5 mg modified-release hard capsules
Aluminium/PVC/PE/PVDC perforated unit dose blisters in pack sizes of 20, 30, 50 or 100 modified-release hard capsules.
HDPE bottles with polypropylene (PP) screw caps and seal liner in packs of 20, 30, 50 or 100 modified-release hard capsules.

Ambinet XL 10 mg, 20 mg, 30 mg, 40 mg modified-release hard capsules
Aluminium/PVC/PE/PVDC perforated unit dose blisters in pack sizes of 30, 50 or 100 modified-release hard capsules.
HDPE bottles with polypropylene (PP) screw caps and seal liner in packs of 30, 50 or 100 modified-release hard capsules.

Ambinet XL 50 mg, 60 mg modified-release hard capsules
Aluminium/PVC/PE/PVDC perforated unit dose blisters in pack sizes of 30 or 40 modified-release hard capsules.
HDPE bottles with polypropylene (PP) screw caps and seal liner in packs of 30 or 40 modified-release hard capsules

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Macarthys Laboratories Limited
Bampton Road, Harold Hill
Romford, Essex
RM3 8UG, United Kingdom

Manufacturer
Develco Pharma GmbH
Grienmatt 27
DE-79650 Schopfheim
Germany

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