PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

Attent XR 5 mg Attent XR 20 mg
Attent XR 10 mg Attent XR 25 mg
Attent XR 15 mg Attent XR 30 mg

Extended release capsules

Each Attent XR 5 mg extended release capsule contains:

1.25 mg dextroamphetamine saccharate
1.25 mg amphetamine aspartate monohydrate
1.25 mg dextroamphetamine sulfate
1.25 mg amphetamine sulfate

The total equivalent amount of amphetamine is 3.1 mg.

Each Attent XR 10 mg extended release capsule contains:

2.5 mg dextroamphetamine saccharate
2.5 mg amphetamine aspartate monohydrate
2.5 mg dextroamphetamine sulfate
2.5 mg amphetamine sulfate

The total equivalent amount of amphetamine is 6.3 mg.

Each Attent XR 15 mg extended release capsule contains:

3.75 mg dextroamphetamine saccharate
3.75 mg amphetamine aspartate monohydrate
3.75 mg dextroamphetamine sulfate
3.75 mg amphetamine sulfate

The total equivalent amount of amphetamine is 9.4 mg.

Each Attent XR 20 mg extended release capsule contains:

5.0 mg dextroamphetamine saccharate
5.0 mg amphetamine aspartate monohydrate
5.0 mg dextroamphetamine sulfate
5.0 mg amphetamine sulfate

The total equivalent amount of amphetamine is 12.5 mg.

Each Attent XR 25 mg extended release capsule contains:

6.25 mg dextroamphetamine saccharate
6.25 mg amphetamine aspartate monohydrate
6.25 mg dextroamphetamine sulfate
6.25 mg amphetamine sulfate

The total equivalent amount of amphetamine is 15.6 mg.

Each Attent XR 30 mg extended release capsule contains:

7.5 mg dextroamphetamine saccharate
7.5 mg amphetamine aspartate monohydrate
7.5 mg dextroamphetamine sulfate
7.5 mg amphetamine sulfate

The total equivalent amount of amphetamine is 18.8 mg.

For information regarding inactive ingredients and allergens, see section 2 "Important information about some of the ingredients of the medicine" and section 6 – "Additional information".

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have additional questions, refer to the doctor or the pharmacist.

This medicine has been prescribed as a treatment for you or for your child. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

The medicine contains amphetamines, which have a potential for abuse.
Long term use may cause addiction.
The abuse of amphetamines may cause sudden death and serious cardiac side effects.

1. WHAT IS THE MEDICINE INTENDED FOR?

The medicine contains a mix of amphetamine salts, which are substances that stimulate the central nervous system, and is intended for the treatment of ADHD = attention deficit hyperactivity disorder.

Therapeutic class: a mix of amphetamine salts that stimulate the central nervous system.

The medicine may help increase attention and lower the impulsiveness and hyperactivity threshold in patients suffering from attention deficit hyperactivity disorder. This medicine should be used as part of an overall ADHD treatment program which may include other methods (psychological, educational, social).

2. BEFORE USING THE MEDICINE

Do not use the medicine if you or your child:

- Suffer from a heart disease or arteriosclerosis
- Suffer from moderate or severe hypertension
- Suffer from overactivity of the thyroid
- Suffer from glaucoma
- Suffer from severe anxiety, stress or agitation
- Suffer or have previously suffered/have a history of addiction to alcohol or medicines
- Are taking an antidepressant of the monoamine oxidase inhibitors (MAOIs) group or if you have taken such a medicine within the past two weeks
- Are sensitive (allergic) to amphetamines, to other stimulant medicines or to one of the other ingredients of the medicine

Special warnings regarding the use of the medicine

Before starting the treatment tell the doctor if you or your child are suffering or have previously suffered from any medical problem or if there is a family history, including:

- Heart disease, heart defect, high blood pressure
- Mental problems, psychosis, mania, bipolar disease, depression, suicide
- Tics (involuntary muscle reactions), Tourette's syndrome
- Liver problems
- Kidney problems
- End-stage renal disease (ESRD)
- Thyroid problems
- Seizures or an abnormal finding in brain wave test (EEG test)
- Blood circulation problems in the fingers and toes. Numbness, pain, skin discoloration, sensitivity to temperature in the fingers or toes
- Abuse of or addiction to alcohol, prescription medicines or street drugs
- If you are pregnant or planning to become pregnant
- If you are breastfeeding or planning to breastfeed

Additional warnings

The doctor will consider performing a heart function test before starting treatment with the medicine.

The doctor will consider regular blood pressure and heart rate tests during the period of treatment with the medicine.

Drug interactions

If you or your child are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.

Especially inform your doctor or pharmacist if you or your child are taking:

- Antidepressants, including medicines from the monoamine oxidase inhibitors group (MAOIs). See "Do not use the medicine if you or your child"
- Antipsychotic medicines
- Lithium
- Narcotic analgesics
- Medicines for the treatment of hypertension
- Medicines for the treatment of seizures
- Medicines for the relief of cold or anti-allergy medicines that contain decongestants
- Medicines for the treatment of hyperacidity of the stomach (such as sodium bicarbonate, omeprazole)
- Blood thinning medicines
- Serotonergic medicines (from the SNRI family, from the SSRI family, triptans, tricyclic antidepressants, fentanyl, lithium, tramadol, tryptophan, buspirone, St. John's Wort)
- Quinidine, ritonavir
- Acetazolamide

You should be familiar with the medicines you or your child are taking. Prepare and keep a list of medicines in order to show to the pharmacist or doctor as needed.

Pregnancy

Consult the doctor before taking the medicine if you are pregnant or if you consider becoming pregnant, as the medicine may cause harm to your fetus.

Breastfeeding

The medicine passes into breast milk. Do not breastfeed while using the medicine.

Use in children

This medicine is not intended for children under 6 years of age. No information is available regarding the safety and efficacy of using the medicine in children under the age of 6.

Driving and operating machinery

The medicine may impair your ability to drive and operate dangerous machinery. The patient must therefore exercise the appropriate degree of caution in carrying out these actions.

Use of the medicine and food

The medicine may be taken with or without food.

Important information about some of the ingredients of the medicine

This medicine contains sugar. If you have been told by the doctor that you or your child have an intolerance to some sugars, refer to the doctor before taking this medicine. The amount of sugar: Attent XR 5 mg – about 46 mg sugar, Attent XR 10 mg – about 91 mg sugar, Attent XR 15 mg – about 136 mg sugar, Attent XR 20 mg – about 181 mg sugar, Attent XR 25 mg – about 226 mg sugar, Attent XR 30 mg – about 271 mg sugar.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain.

The dosage and treatment regimen will be determined only by the doctor.

Take this medicine exactly as prescribed. The doctor will adjust the dosage individually for you or for your child.

Take this medicine once a day, in the morning after you wake up.

Attent XR capsule is an extended release capsule which releases the medicine into your body during the day.

Swallow the capsule whole with water.

If you have difficulty swallowing the capsule whole, you may open it and sprinkle its content over a tablespoon of apple sauce.

Swallow the whole mixture of apple sauce and medicine immediately without chewing. Afterwards, drink water.

Do not chew or crush the capsule or the medicine inside the capsule.

Do not exceed the recommended dose.

Tests and follow-up

- Occasionally the doctor may stop the treatment to evaluate the attention deficit hyperactivity disorder
- The doctor may perform regular heart and blood pressure tests during the period of treatment with the medicine
- In children, the weight and height should be checked frequently

The doctor will consider treatment cessation in case the results indicate any problem.

If you took an overdose or if a child accidentally swallowed this medicine, refer to the doctor or to a hospital emergency room immediately and bring the package of the medicine.

If you forgot to take the medicine

If you forgot to take this medicine at the required time, do not take a double dose. Take the next dose at the scheduled time and consult a doctor.

Follow the treatment as recommended by the doctor. Even if there is an improvement in your health condition, do not stop the treatment with the medicine without prior consultation with the doctor or pharmacist.

How can you contribute to the success of the treatment?

Do not take medicines in the dark! Check the label and the dose every time you take the medicine. Wear glasses if you need them.

If you have any other questions regarding the use of the medicine, consult the doctor or the pharmacist.

4. SIDE EFFECTS

As with any medicine, using Attent XR may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

The following side effects have been reported after the use of stimulant medications:

1- Heart related problems

- Sudden death in patients suffering from a defect or impaired function of the heart
- Stroke or heart attack in adults
- Increased blood pressure and heart rate

Refer immediately to the doctor if you or your child experience effects that indicate heart problems while using the medicine, such as chest pain, breathing difficulties, or fainting.

2- Psychiatric problems

All patients

- The appearance of new behavioral and thought problems or worsening of these effects
- The appearance of a new bipolar disease or worsening of an existing bipolar disease
- The appearance of a new aggressive or hostile behavior or worsening of them

Children and teenagers

- The appearance of new psychotic symptoms (such as hearing voices, believing in things that are not real and are suspicious) or new manic symptoms.

Immediately refer to the doctor in case you or your child are suffering from the appearance of new mental problems or any new mental symptoms or from worsening of them while taking the medicine, especially seeing or hearing things that are not real, believing in things that are not real and are suspicious.

3- Blood circulation problems in the fingers and toes (peripheral vascular problems, including Raynaud's syndrome)

- Numbness, coldness, pain in the fingers and toes
- Color change from pale to blue and to red in the fingers and toes

Report to the doctor immediately if these effects develop or if you notice unexplained wounds that appear in the fingers or toes while taking the medicine.

Additional severe side effects include:

- Slowing of growth (weight and height) in children
- Seizures, mainly in patients with a history of seizures
- Changes in vision or blurred vision
- Tics (involuntary muscle reactions)
- Serotonin syndrome – an effect that may be life-threatening, which may occur when medicines such as this are taken with certain other medicines (serotonergic medicines such as SNRIs, SSRIs, triptans, tricyclic antidepressants, fentanyl, lithium, tramadol, tryptophan, buspirone, St. John's Wort etc.) and in overdose situations. Symptoms of serotonin syndrome may include:
  - Emotional turmoil, hallucinations, coma or other changes in mental condition
  - Problems controlling movements or muscle contractions
  - Fast heartbeat
  - High or low blood pressure
  - Sweating or fever
  - Nausea or vomiting
  - Diarrhea
  - Muscle rigidity or tension

  Stop the treatment with the medicine and initiate supportive treatment.

Common side effects

- Headache
- Abdominal pain
- Sleeping problems
- Weight loss
- Dry mouth
- Rapid heartbeat
- Decreased appetite
- Nervousness
- Mood swings
- Dizziness

Additional side effects

Cardiac effects: palpitations, cardiomyopathy (cardiac muscle disease).

Central nervous system: psychiatric effects, overstimulation, restlessness, nervousness, euphoria, movement disorders, dysphoria (dissatisfied mood), depression, tremor, aggressiveness, tics, anger, excessive talkativeness (logorrhea), skin picking disorder (dermatilomania), tingling sensation and teeth grinding.

Eyes: blurry vision, dilated pupils.

Digestive system: unpleasant taste, constipation.

Allergic reactions: hypersensitivity including angioedema (swelling of the skin and mucosa, usually in the area of the face, tongue and throat) and anaphylaxis (acute allergic reaction that may be life-threatening), serious skin rashes including Stevens-Johnson syndrome and toxic epidermal necrolysis (manifested by the formation of blisters and flaking of the skin).

Endocrine system: changes in libido, impotence, frequent or prolonged erection.

Skin: hair loss.

Musculoskeletal: rhabdomyolysis.

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Reporting side effects

Side effects may be reported to the Ministry of Health by clicking on the link "Report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link: https://sideeffects.health.gov.il

5. HOW TO STORE THE MEDICINE?

Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.

Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.

Store at a temperature below 25°C.

Use the medicine up to 60 days after first opening the bottle, and no later than the expiry date.

Do not discard medicines via wastewater or the trash. Ask your pharmacist how to dispose of medicines no longer in use. These measures will help to protect the environment.

6. ADDITIONAL INFORMATION

In addition to the active ingredients, the medicine also contains:

Sugar Spheres (sucrose and corn starch), Ammonio Methylacrylate copolymer, Talc, Hydroxypropyl cellulose, Triethyl citrate.

The capsule body, capsule cap and ink contain:

5 mg: Gelatin, Titanium Dioxide, Yellow Iron Oxide, FD&C Blue # 1, Red Iron Oxide

10 mg: Gelatin, Titanium Dioxide, FD&C Blue # 1, D&C Yellow # 10

15 mg: Gelatin, Titanium Dioxide, Yellow Iron Oxide, Red Iron Oxide, D&C Yellow # 10

20 mg: Gelatin, Titanium Dioxide, FD&C Blue # 1

25 mg: Gelatin, Titanium Dioxide, D&C Yellow # 10

30 mg: Gelatin, Titanium Dioxide, Yellow Iron Oxide, Red Iron Oxide

and:

FD&C Red # 40 (E129), FD&C Blue # 2 (E132), FD&C Blue # 1 (E133), D&C Yellow # 10

What does the medicine look like and what are the contents of the package?

Attent XR 5 mg:

Opaque capsules with orange capsule body and light blue capsule cap. R and 3062 are printed in black on the body and cap of the capsule.

Attent XR 10 mg:

Opaque capsules with ivory capsule body and light blue capsule cap. R and 3059 are printed in black on the body and cap of the capsule.

Attent XR 15 mg:

Opaque capsules with orange capsule body and ivory capsule cap. R and 3063 are printed in black on the body and cap of the capsule.

Attent XR 20 mg:

Opaque capsules with light blue capsule body and light blue capsule cap. R and 3060 are printed in black on the body and cap of the capsule.

Attent XR 25 mg:

Opaque capsules with ivory capsule body and ivory capsule cap. R and 3064 are printed in black on the body and cap of the capsule.

Attent XR 30 mg:

Opaque capsules with orange capsule body and orange capsule cap. R and 3061 are printed in black on the body and cap of the capsule.

Package contents:

The capsules are packed in a plastic bottle with a child proof cap. Each package contains 30 extended release capsules.

Not all package sizes and dosages may be marketed.

Name and address of the manufacturer and marketing authorization holder:

Teva Israel Ltd., 124 Dvora HaNevi'a St., Tel Aviv 6944020.

This leaflet was approved in November 2022.

Registration numbers of the medicine in the National Drug Registry of the Ministry of Health:

5 mg	170-89-35975
10 mg	170-90-35994
15 mg	170-91-35995
20 mg	170-92-35996
25 mg	170-93-35997
30 mg	170-94-35988

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