

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

The medicine is dispensed with a doctor's prescription only

Attent 10 mg tablets Attent 20 mg tablets Attent 30 mg tablets

Composition

Each Attent 10 mg tablet contains:

2.5 mg of each of the following ingredients:

Dextroamphetamine saccharate
Amphetamine aspartate monohydrate
Dextroamphetamine sulfate
Amphetamine sulfate

The total equivalent amount of amphetamine is 6.3 mg.

Each Attent 20 mg tablet contains:

5 mg of each of the following ingredients:

Dextroamphetamine saccharate
Amphetamine aspartate monohydrate
Dextroamphetamine sulfate
Amphetamine sulfate

The total equivalent amount of amphetamine is 12.6 mg.

Each Attent 30 mg tablet contains:

7.5 mg of each of the following ingredients:

Dextroamphetamine saccharate
Amphetamine aspartate monohydrate
Dextroamphetamine sulfate
Amphetamine sulfate

The total equivalent amount of amphetamine is 18.8 mg.

For information on inactive and allergenic ingredients in the preparation, see in section 2 "Important information about some of the ingredients of the medicine" and section 6 – "Further information".

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for the treatment of your ailment. 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 can be taken by adults and also by children and therefore, the information in this leaflet is also intended for children taking this medicine.

The medicine contains amphetamines, which have potential to be misused. Taking for a long time may lead to dependence. Misuse of amphetamines may cause sudden death and severe cardiac side effects.

1. WHAT IS THE MEDICINE INTENDED FOR?

The medicine contains a mix of amphetamine salts, which are central nervous system stimulants, and is intended for use as follows:

- Treatment of Attention Deficit Hyperactivity Disorder (ADHD). The medicine helps to increase alertness and lower the impulsiveness and hyperactivity threshold in patients suffering from ADHD. This medicine should be used within the framework of an ADHD rehabilitation program which includes counseling or other therapies.

- Treatment of narcolepsy (an ailment characterized by uncontrollable daytime sleep attacks).

Therapeutic group

A mix of amphetamine salts.

2. BEFORE USING THE MEDICINE

Do not use the medicine if you are suffering from:

- A heart disease or calcification of the arteries
- Moderate or severe hypertension
- Hyperthyroidism
- Glaucoma
- Severe anxiety, stress or agitation
- History of addiction to alcohol or medicines
- If you are taking monoamine oxidase inhibitors (MAOIs)-type antidepressant, or if you have taken such a medicine within the past two weeks
- Do not use this medicine if there is a known sensitivity to amphetamines, other stimulant medicines or to one of the other ingredients of the medicine

Special warnings regarding use of the medicine

Before starting the treatment, tell the doctor if you are suffering, or have suffered in the past, from any medical problem or if you have a family history, including:

- Heart disease, heart defect, hypertension
- Mental problems, including psychosis, mania, bipolar disease, depression, family history of suicide
- Tics, Tourette's syndrome
- Liver or kidney problems
- Thyroid gland problems
- Seizures or abnormal brain wave test results (EEG test)
- Problems with blood circulation in the fingers and toes

Additional warnings

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

The doctor must consider performing regular blood pressure and heartbeat tests during the course of treatment with the medicine.

Drug interactions

If you are taking, or if you have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. In particular, inform the doctor or pharmacist if you are taking:

- Antidepressants, including monoamine oxidase inhibitors (MAOIs), see in section 2 "Do not use the medicine if you are suffering from"
- Medicines for treatment of hypertension
- Anti-seizure medicines
- Cold medicines or anti-allergy medicines that contain decongestants
- Medicines to treat hyperacidity of the stomach
- Blood-thinning medicines

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

Pregnancy

Consult the doctor before taking the medicine if you are pregnant, or if you are considering becoming pregnant.

Breastfeeding

The medicine passes into breast milk. Avoid breastfeeding while using the medicine.

Use in children

This medicine is not intended for use in children under 3 years of age.

Driving and operating machinery

The medicine may impair the ability to drive and to operate dangerous machinery.

Use of the medicine and food

The medicine can be taken with or without food.

Important information about some of the ingredients of the medicine

This medicine contains less than 23 mg sodium per tablet, namely, it is considered sodium-free. This medicine contains sucrose. If you have been told by the doctor that you have an intolerance to certain sugars, refer to your doctor before taking this medicine. The amount of sucrose: Attent 10 mg – approximately 98 mg sucrose, Attent 20 mg – approximately 93 mg sucrose, Attent 30 mg – approximately 140 mg sucrose.

Attent 20 mg and 30 mg tablets contain FD&C Yellow No. 6 Aluminium Lake, which may cause allergic effects.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.

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

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

It is preferable to avoid taking the medicine late in the evening since it may make it difficult to fall asleep.

To take half a dose, the tablets can be halved on the bisect line.

Do not exceed the recommended dose.

Tests and follow-up

- The doctor will periodically consider discontinuation of treatment to reassess the ADHD.
- The doctor must consider performing regular blood, heart and blood pressure tests during the course of treatment with the medicine.
- The weight and height of children should be measured.

The doctor will consider discontinuing the treatment if the results indicate any problem.

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

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 regular time and consult the doctor.

Adhere to the treatment as recommended by the doctor. Even if there is an improvement in your health, do not stop treatment with the medicine without first consulting 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 each time you take a medicine. Wear glasses if you need them. If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

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

The following side effects were reported after use of stimulant medicines:

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

2- Psychiatric problems

All patients: children, teenagers and adults

- Development of behavioral disturbances or thinking disturbances or worsening of these effects.
- Development or worsening of pre-existing bipolar disease.
- Development or worsening of aggressive or hostile behavior.

Children and teenagers

- Psychotic effects (e.g., hearing voices) or mania.

Refer to the doctor immediately if you or your child experience worsening of or new mental effects while using the medicine, especially hallucinations or suspicion.

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

Use of the medicine may cause blood circulation problems in the fingers and toes. These problems can be manifested by a feeling of numbness, coldness or pain in the fingers or toes, or a discoloration of the fingers or toes from pale to blue and to red. **Report to the doctor immediately if these effects develop or if signs of unexplained wounds develop in the fingers or toes while taking the medicine.**

Stop the treatment and refer to the doctor immediately if signs of hypersensitivity occur, such as:

Urticaria (an allergic skin reaction manifested by rash and itching), rash.

Other side effects

- Slowing of growth (height and weight) in children
- Seizures, mainly in patients who suffered from them in the past
- Eyesight changes or blurred vision
- Serotonin syndrome – a problem that may be life-threatening, called serotonin syndrome, which may occur when medicines such as Attent are taken with certain other medicines. Symptoms of serotonin syndrome can include:
 - Agitation, hallucinations, coma or other mental changes
 - Problems controlling your movements or muscle contractions
 - Rapid heartbeat
 - High or low blood pressure
 - Sweating or fever
 - Nausea or vomiting
 - Diarrhea
 - Muscle rigidity or tension

Common side effects

- Stomachache
- Decreased appetite
- Nervousness

Additional side effects

Cardiac effects: palpitations, cardiomyopathy (a disease of the heart muscle).

Central nervous system: psychotic effects, excessive irritation, restlessness, nervousness, euphoria, movement disorders, dysphoria (dissatisfied mood), depression, tremor, aggressiveness, tics, anger, logorrhea, self-harm to the skin (dermatillomania).

Eyes: dilation of the pupil.

Digestive system: dry mouth, unpleasant taste, diarrhea, constipation, ischemia (decreased blood supply) of the intestine, anorexia and weight loss.

Allergic reactions: hypersensitivity, including angioedema and anaphylaxis, serious skin rashes, including Stevens-Johnson syndrome

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 are suffering from a side effect not mentioned in the leaflet, consult with the doctor.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:

<https://sideeffects.health.gov.il>

5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants in order 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) that appears on the package. The expiry date refers to the last day of that month.

Store at a temperature below 25°C and protect from light.

The medicine can be used for up to 90 days after first opening the bottle and no later than the expiry date.

Do not discard medicines in the wastewater or waste bin. Ask the pharmacist how to dispose of medicines that are not in use. These measures will help protect the environment.

6. FURTHER INFORMATION

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

Compressible sugar, microcrystalline cellulose, corn starch, saccharin sodium, magnesium stearate and colloidal silicon dioxide.

10 mg tablets also contain

FD&C Blue No. 1 Aluminium Lake

20 mg and 30 mg tablets also contain FD&C Yellow No. 6 Aluminium Lake (sunset yellow FCF)

What the medicine looks like and the contents of the package

Attent 10 mg:

Blue, oval tablet, debossed with "b" over "972" between two horizontal lines on one side. On the other side, debossed with "1" and "0" on both sides of a bisect line [1 | 0] and between two horizontal lines.

Attent 20 mg:

Peach, oval tablet, debossed with "b" over "973" between two horizontal lines on one side. On the other side, debossed with "2" and "0" on both sides of a bisect line [2 | 0] and between two horizontal lines.

Attent 30 mg:

Peach, oval tablet, debossed with "b" over "974" between two horizontal lines on one side. On the other side, debossed with "3" and "0" on both sides of a bisect line [3 | 0] and between two horizontal lines.

Contents of the package:

Each plastic bottle contains 30 tablets and a desiccant.

Do not swallow the desiccant and leave it in the bottle until completion of use.

Name of Manufacturer and Licence Holder and its Address

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

This leaflet was revised in February 2022 according to MOH guidelines.

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

10 mg 154.13.34222

20 mg 154.14.34224

30 mg 154.15.34225