

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, 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 can cause serious side effects, including:**

Abuse and addiction:

Attent has a high chance for abuse or misuse that may lead to addiction.

Abuse and misuse of Attent, other amphetamine-containing medicines and methylphenidate-containing medicines can lead to overdose and death. This risk is increased with higher dosages of Attent or when it is administered in ways that are not approved, such as snorting or injection.

The doctor should check your or your child's risk for abuse, misuse or addiction before starting treatment with Attent and continue monitoring throughout the treatment.

Attent may lead to physical dependence after prolonged use, even if taken as directed by the doctor .

Do not give Attent to anyone else.

Keep the medicine in a safe place and dispose of any unused medicine as required.

Tell the doctor if you or your child has ever abused or been dependent on alcohol, prescription medicines or street drugs.

Risks to people with serious cardiac disease:

Sudden death has been reported in people with structural cardiac abnormalities or other serious cardiac disease.

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 have a known sensitivity to amphetamines or any of the additional ingredients of the medicine; see “Important information about some of the ingredients of the medicine” in section 2 and the list of ingredients contained in the medicine in section 6 – “Further information”.
- you are taking, or have taken within the past 14 days, a monoamine oxidase inhibitor (MAOI)-type antidepressant, including the antibiotic linezolid or methylene blue by injection.

Special warnings regarding use of the medicine

Before starting treatment with the medicine, the doctor should perform a careful examination of your or your child's heart function.

During the course of treatment with the medicine, the doctor should routinely check your or your child's blood pressure and pulse.

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

- Heart problems, heart disease, heart defect, hypertension
- Mental problems, including psychosis, mania, bipolar disease, depression, family history of suicide
- Kidney problems
- Seizures or abnormal brain wave test results (EEG test)
- Problems with blood circulation in the fingers and toes
- Repeated movements or sounds – tics or Tourette's syndrome

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:

- Selective serotonin reuptake inhibitors (SSRIs)
- Serotonin norepinephrine reuptake inhibitors (SNRIs)
- Medicines called triptans for treatment of migraine headaches
- Tricyclic antidepressants
- Lithium
- Fentanyl
- Tramadol
- Tryptophan
- Buspirone
- St. John's wort
- Antidepressants, including monoamine oxidase inhibitors (MAOIs); see in section 2 “Do not use the medicine if”
- Medicines for treatment of hypertension
- Anti-seizure medicines
- Cold medicines or anti-allergy medicines that contain decongestants
- Medicines to treat hyperacidity of the stomach

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

If you are pregnant or plan to become pregnant, consult the doctor before taking the medicine. It is not known if Attent is harmful to the unborn baby. Inform the doctor if you become pregnant while taking the medicine.

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.

Use of the medicine and food

The medicine can be taken with or without food.

Driving and operating machinery

Do not drive, operate dangerous machines or engage in other dangerous activities until you learn how the medicine affects you.

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.

See “Serious side effects including: **Abuse and addiction**” at the beginning of this leaflet.

Heart problems

Increased blood pressure and heart rate.

Refer to a doctor or proceed to a hospital immediately if you or your child experiences effects that reflect heart problems while using the medicine, such as chest pains, shortness of breath or fainting.

Psychiatric problems

- Development of behavioral disturbances or thinking disturbances or worsening of these effects.
- Development or worsening of pre-existing bipolar disease.
- Onset of new psychotic effects (e.g., hearing voices, hallucinations or believing in things that do not exist) or new effects of mania.

Refer to a doctor immediately if you or your child experiences worsening or new mental effects while using the medicine, especially hearing voices, hallucinations, believing in things that do not exist or new symptoms of mania.

- **Slowed growth (height and weight)** in children.
- **Seizures.**

- **Circulation problems in the fingers and toes (peripheral vasculopathy, including Raynaud's syndrome).** Signs may manifest by numb, cold or painful fingers or a change in color of the fingers from pale, to blue and to red.

Tell the doctor immediately if these effects develop or if signs of unexpected sores develop in the fingers or toes while taking the medicine.

- **Serotonin syndrome** – a potentially life-threatening syndrome that can occur when medicines such as Attent are taken with certain other medicines. Stop taking the medicine and refer to a doctor immediately if signs or effects of serotonin syndrome develop:

- Agitation, hallucinations, coma
- Confusion
- Fast heartbeat
- Dizziness
- Flushing
- Changes in blood pressure
- Sweating or fever
- Seizures
- Loss of coordination
- Nausea, vomiting, diarrhea
- Muscle stiffness or tightness
- High body temperature (hyperthermia)

- **Worsening or new tics or worsening of Tourette's syndrome** – tell the attending doctor

Most 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: blurred vision, 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: rash, allergic rash, hypersensitivity, including angioedema and anaphylaxis, serious skin rashes, including Stevens-Johnson syndrome and toxic epidermal necrolysis.

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 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 (sucrose and maltodextrin), 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 I 0] 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 I 0] 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 I 0] 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 License Holder and its Address: Teva Israel Ltd., 124 Dvora Hanevi'a St., Tel Aviv 6944020

Revised in November 2024.

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