

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

The medicine is dispensed with  
a doctor's prescription only

**Attent 5 mg tablets  
Attent 10 mg tablets  
Attent 20 mg tablets  
Attent 30 mg tablets**

**Composition**

**Each Attent 5 mg tablet contains**

1.25 mg of each of the following ingredients:  
Dextroamphetamine Saccharate  
Amphetamine Aspartate Monohydrate  
Dextroamphetamine Sulfate  
Amphetamine Sulfate  
The total equivalent amount of amphetamine is 3.13 mg

**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 the list of inactive ingredients in the preparation, see section 6 – “Further Information”.

**Read this 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.**

**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 preparation 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 a monoamine oxidase inhibitor (MAOI)-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 any 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 condition or if you have a family history, including:**

- a 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.

**⊠ If you are taking, or 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 section 2 “Do not use the preparation 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 this medicine.

**⊠ Use in children**

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

**⊠ Driving and use of 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.

**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 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.

Attent 10 mg, 20 mg and 30 mg tablets: to take half a dose, the tablet can be halved on the bisect line.

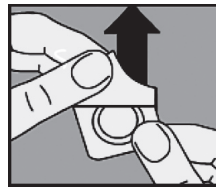
Attent 5 mg tablets: to ease swallowing, the tablet can be divided into smaller pieces.

**Do not exceed the recommended dose.**

**Directions for use:**

To remove the tablet from the blister: Peel the covering from the inner corner of one unit, as shown in the illustration.

To facilitate removal of the tablet, first fold the blister along one of the perforation lines.



**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.

**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 this 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 this medicine, especially hallucinations or suspicion.**

**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

Use of this 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 this medicine.**

**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**

- Stomach ache
- Decreased appetite
- Nervousness

**Additional side effects**

Central nervous system: restlessness, insomnia, euphoria, depression, tremor, headache

Digestive system: dry mouth, unpleasant taste, diarrhea, constipation, loss of appetite and weight loss

Endocrine system: changes in libido, impotence

Skin: hair loss

**If a side effect occurs, if any of the side effects worsen, or if you are suffering from a side effect not mentioned in the leaflet, consult the doctor.**

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](http://www.health.gov.il)) that directs you to the online form for reporting side effects, or by entering the link: <https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.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 of children and/or infants in order to avoid poisoning. Do not induce vomiting without explicit instruction from the doctor.

Do not use the medicine after the expiry date (Expiry date) that appears on the package.

The expiry date refers to the last day of that month.

Bottle package: Do not use after 60 days from the day it was dispensed.

Blister package: Use according to the expiry date on the package.

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

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 ingredient, the medicine also contains:**

Colloidal silicon dioxide, compressible sugar, corn starch, magnesium stearate, microcrystalline cellulose and saccharin sodium.

5 mg and 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

Each 5 mg tablet contains:

approximately 0.22 mg sodium and approximately 49 mg sucrose

Each 10 mg tablet contains:

approximately 0.45 mg sodium and approximately 98 mg sucrose

Each 20 mg tablet contains:

approximately 0.45 mg sodium and approximately 93 mg sucrose

Each 30 mg tablet contains:

approximately 0.67 mg sodium and approximately 140 mg sucrose

**What the medicine looks like and the contents of the package**

What the tablet looks like:

**Attent 5 mg:**

Blue oval tablet, debossed with “b” over “971” between two horizontal lines on one side. On the other side, debossed with “5” above two lines perpendicular to each other.

**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:

**Bottle package**

Original container: Each plastic bottle of 100 tablets contains a desiccant.

Do not swallow the desiccant!

**Blister package**

Each package contains 30 tablets.

It is possible that not all packages are marketed.

**License Holder**

Abic Marketing Ltd., P.O.B. 8077, Netanya

**Name of Manufacturer and its Address**

Barr Laboratories Inc.,

Forest, Virginia 24551, USA

This leaflet was checked and approved by the Ministry of Health in March 2017.

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

5 mg 154.12.34220.00

10 mg 154.13.34222.00

20 mg 154.14.34224.00

30 mg 154.15.34225.00

