

AVONEX[®] 30µg/0.5ml
(interferon beta-1a)

PACKAGE LEAFLET
Solution for Injection

Read all of this leaflet carefully before you start using this medicine

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effect not listed in this leaflet, please tell your doctor, health care provider, or pharmacist.

In this leaflet:

1. What AVONEX is and what it is used for
2. Before you use AVONEX
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Name of this medicine is AVONEX 30 µg /0.5 ml solution for injection
Interferon beta-1a

Each 0.5 ml pre-filled syringe of AVONEX solution for injection contains 30 micrograms (µg) (6 million IU) of the active

ingredient, interferon beta-1a.

The other ingredients are: Sodium acetate, trihydrate; acetic acid, glacial; arginine hydrochloride, polysorbate 20 and water for injections.

Marketing Authorisation Holder:

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United Kingdom

Manufacturer:

Biogen Idec Denmark Manufacturing ApS,
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1. WHAT AVONEX IS AND WHAT IT IS USED FOR

AVONEX is provided as a ready to use solution for injection. In a box of AVONEX there are four pre-filled syringes, each containing 0.5 ml of a clear, colourless solution. Each syringe is packed in a sealed plastic tray, which also contains one injection needle for intramuscular use (IM).

Interferon beta-1a belongs to a group of substances, which help regulate your body's immune system.

AVONEX is used to treat relapsing forms of multiple sclerosis (MS). A relapse is when the symptoms of MS flare-up then improve or disappear. AVONEX has been shown to be effective in slowing the progression of the disease and reducing the frequency of relapses.

AVONEX may also be used if you have only experienced the possible effects of MS once, but your doctor considers that you will develop MS.

2. BEFORE YOU USE AVONEX

Do not use AVONEX if any of the following apply to you:

- If you are hypersensitive (allergic) to interferon beta, or any other of the other ingredients in AVONEX
- If you suffer from severe depression or think about committing suicide

Do not start using AVONEX if you are pregnant.

Take special care with AVONEX if you have or have had in the past:

- Depression or problems affecting your moods

- Thoughts about committing suicide
- Epilepsy or other seizure disorders not controlled by medication
- Serious kidney or liver problems
- A bone marrow disorder, possibly causing an increased risk of infection, bleeding or anaemia
- Problems with your heart, possibly causing symptoms such as chest pain (angina), particularly after any activity; swollen ankles, shortness of breath (congestive heart failure); or an irregular heart beat (arrhythmias).

Changes in your mood, thoughts about suicide, feeling unusually sad, anxious or worthless,

should be reported to your doctor immediately.

If you have ever had any of the conditions described above talk to your doctor as you may need some additional advice or need to be monitored more closely. If any of the above conditions worsen whilst you are using AVONEX, talk to your doctor immediately.

If you are currently taking a medicine that has the potential to cause liver problems, or you drink excessive amounts of alcohol, your doctor may want you to have blood tests to ensure your liver is still working properly.

If you have to visit the hospital or family doctor for any treatment or for a blood test, remember to tell the healthcare professional /doctor that you are receiving AVONEX as it may affect the results of these tests.

AVONEX should not be used in children below the age of 12 years.

Pregnancy and breast-feeding:

- If you are pregnant you should not start using AVONEX.
- If you could get pregnant, you need to use contraception while you take AVONEX.

- If you are planning a baby or if you become pregnant while you are using AVONEX, tell your doctor. You and your doctor can discuss if you should carry on with treatment.
- If you want to breast-feed, talk to your doctor first.

Driving and using machines:

Certain side effects such as dizziness, that have been experienced by some patients using this medicine, may affect the ability to drive and operate machinery. If you are affected and feel your ability may be impaired, you should avoid driving or using machinery.

Taking other medicines:

No formal drug interaction studies have been carried out with AVONEX in humans but experience suggests that AVONEX does not normally interfere with other medicines. In particular, clinical studies have shown that MS patients can receive AVONEX and corticosteroids or adrenocorticotrophic hormone (ACTH) (treatments used to reduce inflammation) during relapses of their MS.

Talk to your doctor if you are taking any medicine to treat epilepsy or depression. Other interferon containing medicines may reduce the

ability of the body to get rid of some of these medicines, potentially resulting in an increased risk of side effects. It is possible that AVONEX could have a similar effect.

Please tell your doctor or pharmacist if you are taking, or have recently taken, any other medicines including those bought without a prescription or herbal remedies.

AVONEX should be given alone; do not mix with other liquids for injection.

Important information about some of the ingredients of AVONEX:

This medicine is essentially 'sodium free'. It contains less than 23 mg (1 mmol) sodium in each weekly dose.

3. HOW TO USE AVONEX

This medicine should only be used under the strict supervision of a doctor. Always use AVONEX exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Dosage:

Adults and adolescents (≥ 12): The usual dose of AVONEX is the content of 1 pre filled syringe (0.5 ml), corresponding to 30 µg (6 million IU)

of interferon beta-1a, injected once a week. You should use this medicine, if possible, at the same time on the same day each week.

AVONEX should not be used in children below the age of 12 years.

Each syringe of AVONEX contains only one dose. Any liquid remaining in the syringe after injection should be thrown away.

If you have decided to start treatment with Avonex, your doctor may provide you an Avostartclip titration kit. The Avostartclip attaches to the syringe and enables you to

gradually increase your dose of Avonex when you first start treatment. This is to limit flu-like symptoms which some people experience when they start using Avonex. Your doctor or nurse will help you use the Avostartclip titration kit.

Instructions for injection:

AVONEX is for injection into a muscle (intramuscular use). It is recommended that you use a different injection site each week to reduce the risk of irritation to your skin and muscle. You must avoid any area of skin that is bruised, sore or infected or if there is an open wound.

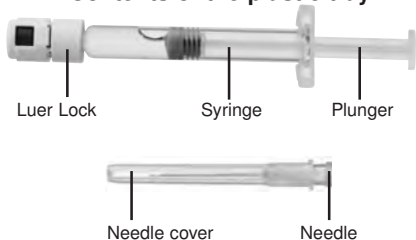
You should use AVONEX under the guidance and supervision of a doctor. You may self-inject if your doctor or MS nurse determines that it is appropriate, and after you have been given proper training in intramuscular injection technique. The following instructions are provided for the person injecting AVONEX.

Your pack of Avonex already includes a needle for injection. It may be possible for your doctor to prescribe you a shorter and thinner needle depending on your body type. Talk to your doctor to see if this is appropriate for you.

Contents of plastic tray

The picture '**Contents of plastic tray**' shows all the components you need for a single dose of AVONEX.

Contents of the plastic tray



Setting up

Remove one sealed plastic tray from the refrigerator. Be sure that the pre-filled syringe and the injection needle are in the sealed plastic tray before proceeding. Leave at room temperature (15-30 °C) for approximately 30 minutes since this will make the injection more comfortable than injecting immediately after removing from the refrigerator.

DO NOT use external heat sources such as hot water to warm the solution for injection.

Wash your hands and find a clean, hard surface to lay out the items needed for administration. Prepare alcohol swabs and sticking plasters (not supplied), if

you have been recommended to use them by your doctor or MS nurse.

Injection

Examine the solution. It should be clear and colourless. If the solution is coloured or contains any floating particles, the pre-filled syringe should not be used.



- 1 -** The syringe has a tamper evident cap. Make sure the cap is intact and has not been opened. If it looks like it has been opened, do not use that syringe. Hold the syringe so the



- 2 -** Attach the injection needle by firmly pressing and turning it.

Failure to firmly attach the injection needle to the syringe could result in leakage.



- 3 -** Use an alcohol swab to clean the skin at one of the recommended intramuscular sites, if you have been advised to do so by your doctor or MS nurse. Allow the skin to dry.



4 - Pull the injection needle cover straight off: **Do not twist.**



5 - With one hand, stretch the skin around the injection site (for example, your upper thigh). Injection of Avonex into the buttocks is not recommended. Relax your muscle.



6 - Insert the injection needle with a quick dart-like thrust at a 90° angle, through the skin into the muscle. The injection needle must penetrate fully. Inject slowly until the syringe is empty.



7 - Pull the injection needle straight out by keeping the skin stretched tightly or squeeze the skin around the injection site. If you have been advised to use alcohol swabs hold one on the injection site. If necessary, apply

a sticking plaster to the site of injection.

Disposing of the rubbish properly

Once you have finished your injection, dispose the pre filled syringe with its injection needle in an appropriate container designed to store used needles safely (a sharps container). Waste paper and used swabs can be put in an ordinary rubbish bin.

Duration of treatment:

Your doctor will tell you how long you need to continue using this medicine. It is important to

continue using AVONEX regularly, and do not make changes unless your doctor advises you.

If you inject more AVONEX than you should:

No case of overdose has been reported. However, if you ever inject more AVONEX than you should, call your doctor or pharmacist immediately for further advice.

If you miss your weekly AVONEX injection:

If you miss your usual weekly dose, inject a dose as soon as you can. You should then leave a week before using AVONEX again. Continue injecting on this 'new' day every

week. Do not double the dose to make up for a missed injection.

4. POSSIBLE SIDE EFFECTS

Like all medicines, AVONEX can have side effects.

The most common side effects are flu-like symptoms such as headache, fever, chills, sweating, muscular aches and pains, feelings of weakness, tiredness and nausea. These may be more common at the start of the treatment and decrease with continuing use. To help reduce these symptoms your doctor may advise you to take a fever reducing painkiller before a

dose of AVONEX and then for 24 hours after each injection. Always talk to your doctor or pharmacist before taking any other medicine whilst you are using AVONEX. If he or she recommends that you take a medicine to reduce these flu-like symptoms, follow the advice carefully: Do not take more than the recommended dose.

A fainting episode may occur after AVONEX injection; it is normally a single episode that usually appears at the beginning of the treatment and does not recur with subsequent injections.

Other less common side effects include:

Hormonal disorders: an under or overactive thyroid

Metabolism and nutrition disorders: loss of appetite, weight gain or weight loss

Psychiatric disorders: difficulty sleeping, depression, (see also information below), nervousness or anxiety, emotional instability, irrational thoughts or hallucinations (seeing or hearing things that are not real), confusion or suicide

Nervous system disorders: numbness including numbness or tingling of the skin, dizziness, seizures or fits and migraine

Heart disorders: palpitations (an awareness of your heart beat) or a rapid or irregular heart beat, heart failure or cardiomyopathy (symptoms may include a reduced ability to exercise, inability to lay flat in bed, shortness of breath or swollen ankles)

Blood vessel disorders: flushing

Breathing disorders: a 'runny' nose, difficulty breathing

Digestion disorders: vomiting, diarrhoea

Liver disorders: liver problems including hepatitis and liver failure (see below for further information)

Skin disorders: increased sweating, night sweats, bruising, hair loss, rash including a nettle or blister like rash, itching or worsening of psoriasis

Muscle and joint disorders: muscle cramp, stiffness, weakness, spasms, aches or pain; pain in the joints, back, neck or extremities (arms and legs); arthritis or systemic lupus erythematosus (an inflammatory condition causing pain and stiffness in muscles, joints and other areas of the body)

Reproductive system disorders: irregularities or changes in your periods (menstrual flow)

General disorders and administration site conditions: injection site reactions including redness, bruising, pain, burning or bleeding (see also information below); pain including chest pain and a general feeling of not being well

Immune system disorders: allergic reactions (see also information below)

Blood tests have found reduced numbers of red or white cells, or blood platelets and various other changes. Possible symptoms resulting from these changes could include tiredness, a reduced ability to fight infection, bruising or unexplained bleeding.

There is a possibility that you may experience temporary effects following an injection that mimic a relapse of your MS symptoms. This could include your muscles feeling very tense or very weak - preventing you from moving as you want to. These symptoms occur rarely, around the time of an injection, and do not last long, but they may occur at any time during treatment. In some cases they are associated with the flu like symptoms described above.

If you notice any of the side effects mentioned above talk to your doctor, pharmacist or MS nurse.

If you notice any of the following side effects you should talk to your doctor immediately:

If you experience any symptom of depression, report it immediately to your doctor.

Inform your doctor immediately if you experience any of the following possible symptoms of a liver problem: jaundice (your skin or the whites of your eyes may appear slightly yellow), widespread itching, nausea and vomiting and easy bruising of the skin.

Serious allergic (hypersensitivity) reactions are rare. Possible symptoms include swelling of the face, lips or tongue, difficulty breathing or a rash. If you have these symptoms, contact your doctor immediately or seek urgent medical attention.

Talk to your doctor or MS nurse if you notice any irritation or skin problems following an injection.

If you notice any side effects not mentioned in this leaflet, please inform your doctor, MS nurse or your pharmacist.

5. STORING AVONEX

- Keep out of the reach and sight of children.
- Store in a refrigerator (2 °C-8 °C).
- DO NOT FREEZE.
- Store in the original package (sealed plastic tray) in order to protect from light.

Avonex can be stored at room temperature (between 15 - 30 °C) for up to one week.

Do not use after the expiry date stated on the label.

Do NOT use AVONEX if you notice:

- The pre filled syringe is broken.
- The sealed plastic tray is damaged or opened.
- The solution is coloured or you can see particles floating in it.
- The tamper evident cap has been broken.

6. FURTHER INFORMATION

Biologix FZ Co is responsible for distribution and drug safety in selected countries of the Middle East.

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To report any side effect(s):

- Saudi Arabia:
 - National Pharmacovigilance Center (NPC)

- o Fax: +966-1-210-7398
 - o E-mail: HYPERLINK
"mailto:npc.drug@sfd.gov.sa"
npc.drug@sfd.gov.sa
 - o Website: www.sfd.gov.sa/npc
 - Other GCC States:
 - Please contact the relevant competent authority
- This is a medicament**
- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.

- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
 - The doctor and the pharmacist are experts in medicine, its benefits and risks.
 - Do not, by yourself, interrupt the period of treatment prescribed for you.
 - Do not repeat the same prescription without consulting your doctor.
 - Keep all medicament out of reach of Children
- Council of Arab Health Ministers
Union of Arab Pharmacists