The content of this leaflet was updated according to the guidelines of the Ministry of Health in October 2017.

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

This medicine can be sold under doctor's prescription only

INTRON A® MULTIDOSE PEN FOR INJECTION 18 MIU
SOLUTION FOR INJECTION

Each pen contains:
Interferon alfa-2b 18 million IU

For a list of inactive ingredients see section 6.1 "**What INTRON A contains**". See also section 2.7 "**Important information about some of the ingredients of INTRON A**".

Read all of this leaflet carefully before you start taking this medicine.
- This leaflet contains concise information about **INTRON A**. If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their medical condition seems similar to yours.
- This medicine is intended for adult patients. This medicine is not intended for children and adolescents under 18 years of age.

1. WHAT INTRON A IS AND WHAT IT IS USED FOR?
1.1 What is INTRON A?
Therapeutic Group: Interferons.
INTRON A (interferon alfa-2b) modifies the response of the body's immune system to help fight infections and severe diseases.

1.2 What is INTRON A used for?
INTRON A is used in adult patients to treat certain disorders that affect the blood, bone marrow, lymph glands, or skin and may extend into the body. Included are hairy cell leukaemia, chronic myelogenous leukaemia, Non-Hodgkin's lymphoma, follicular lymphoma, AIDS-related Kaposi's sarcoma, recurrent or metastatic renal cell carcinoma , and malignant melanoma.
INTRON A is also used in adult patients for the treatment of chronic hepatitis B or C, which are viral infections of the liver.

2. BEFORE YOU USE INTRON A
2.1 Do not use INTRON A:
- if you are allergic to interferon or any of the other ingredients of this medicine (listed in section 6).
- if you have severe heart disease.
- if you have poor kidney or liver function.
- if you have advanced decompensated (uncontrolled) liver disease.
- if you have hepatitis and have been treated recently with medicines that suppress the immune system (other than short-term treatment with cortisone-type medicine).
- if you have a history of seizures (convulsions).
- if you have a history of autoimmune disease, or have had an organ transplant and are taking medicine that suppresses your immune system (your immune system helps protect you from infection).
- if you have thyroid disease that is not well controlled.

- if you are being treated with telbivudine (see section 2.3 "Taking other medicines").

2.2 Special warnings concerning use of INTRON A

Talk to your doctor or pharmacist before using **INTRON A**

- if you are pregnant or planning to become pregnant (see section 2.5 “Pregnancy, breast-feeding and fertility”).
- if you are being treated for mental illness or had treatment in the past for any other nervous or mental disorder, including depression (such as feelings of sadness, dejection) or suicidal or homicidal behaviour (see section 4 “Side Effects”).
- if you have cirrhosis or other liver problems (other than hepatitis B or C).
- if you have psoriasis, it may get worse during treatment with **INTRON A**.
- when receiving **INTRON A**, you may temporarily have a greater risk of getting an infection. Check with your doctor if you think you are getting an infection.
- if you develop symptoms associated with a cold or other respiratory infection, such as fever, cough, or any difficulty in breathing, tell your doctor.
- if you notice unusual bleeding or bruising check with your doctor immediately.
- if you develop symptoms of a severe allergic reaction (such as difficulty in breathing, wheezing, or hives) while on this medicine seek medical help immediately.
- if you are also being treated for HIV (see section 2.3 “Taking other medicines”).
- if you have a current or previous infection with the hepatitis B virus, since your doctor may want to monitor you more closely.
- if you have received an organ transplant, either kidney or liver, interferon treatment may increase the risk of rejection. Be sure to discuss this with your doctor.

Dental and gum disorders, which may lead to loss of teeth, have been reported in patients receiving **INTRON A** and ribavirin combination therapy. In addition, dry mouth could have a damaging effect on teeth and membranes of the mouth during long-term treatment with the combination of **INTRON A** with ribavirin. You should brush your teeth thoroughly twice daily and have regular dental examinations.
In addition some patients may experience vomiting. If you have this reaction, be sure to rinse your mouth thoroughly afterwards.

Tell your doctor if you have ever had a heart attack or a heart problem; if you have a history of breathing irregularities or pneumonia, problems with blood clotting, liver condition, thyroid problems, diabetes, or high or low blood pressure.

Tell your doctor if you have ever been treated for depression or any other psychiatric disorder; confusion; unconsciousness; thoughts of suicide or attempted suicide, or have a history of substance abuse (e.g., alcohol or drugs).

Be sure to tell your doctor if you are taking the Chinese herbal medicine shosaikoto.

2.3 Taking other medicines

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

INTRON A will add to the effects of substances that slow down your nervous system activity, possibly causing drowsiness. Therefore, check with your doctor or pharmacist about drinking alcoholic beverages, or taking sleeping pills, sedatives or strong pain medicines.

Tell your doctor if you are taking theophylline or aminophylline for asthma, and about all other medicines you are taking, or have taken recently, even those not prescribed, as the dose of some medicines may have to be adjusted while you are treated with **INTRON A**.

Patients who also have HIV infection: Lactic acidosis and worsening liver function are side effects associated with Highly Active Anti-Retroviral Therapy (HAART), an HIV treatment. If you are receiving HAART, the addition of **INTRON A** and ribavirin may increase your risk of lactic acidosis and of liver failure. Your doctor will monitor you for signs and symptoms of these conditions (Please be sure to read the ribavirin Patient Leaflet also). Additionally, patients treated with **INTRON A** and ribavirin combination therapy and zidovudine could be at increased risk of developing anaemia (low number of red blood cells).

If you take telbivudine with a pegylated interferon alfa-2a or any type of injectable interferon product, your risk of developing peripheral neuropathy (numbness, tingling and/or burning sensations in the arms and/or legs) is higher. These events may also be more severe. Therefore, the combination of **INTRON A** with telbivudine is contraindicated.

2.4 INTRON A with food and drink and alcohol
While being treated with **INTRON A**, your doctor may want you to drink extra fluids to help prevent low blood pressure.

2.5 Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. In studies in pregnant animals, interferons have sometimes caused miscarriage. The effect on human pregnancy is not known.
If you are prescribed **INTRON A** in combination with ribavirin, ribavirin can be very damaging to an unborn baby, thus both female and male patients must take special precautions in their sexual activity if there is any chance for pregnancy to occur:

- if you are a **girl** or a **woman** of childbearing age, you must have a negative pregnancy test before treatment, each month during treatment, and for the 4 months after treatment is stopped. You must use an effective contraceptive during the time you are taking ribavirin and for 4 months after stopping treatment. This can be discussed with your doctor.
- if you are a **man** who is taking ribavirin, do not have sex with a pregnant woman unless you use a condom. This will lessen the chance for ribavirin to be left in the woman's body. If your female partner is not pregnant now but is of childbearing age, she must be tested for pregnancy each month during treatment and for the 7 months after treatment has stopped. This can be discussed with your doctor. If you are a male patient, you or your partner must use an effective contraceptive during the time you are taking ribavirin and for 7 months after stopping treatment. This can be discussed with your doctor.

It is not known whether this medicine is present in human milk. Therefore, do not breast-feed an infant if you are taking **INTRON A**. In combination therapy with ribavirin, take notice of the respective informing texts of ribavirin containing medicinal products.

2.6 Driving and using machines
Do not drive or use machines if you become drowsy, tired, or confused from using this medicine.

2.7 Important information about some of the ingredients of INTRON A
INTRON A contains less than 1 mmol sodium (23 mg) per 1.2 ml, i.e., essentially "sodium-free".

3. HOW TO USE INTRON A?
Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.
The dosage and duration of treatment will be determined by the doctor only.
Complete the full course of treatment as instructed by the doctor.
Your doctor has prescribed **INTRON A** specifically for you and your current condition; do not share this medicine with anyone else.

Your doctor has determined the exact dosage for administration of **INTRON A** according to your individual needs. The dosage will vary according to the disease being treated. The pen is designed to deliver its

contents of 18 million IU in doses ranging from 1.5 to 6 million IU. The pen will deliver a maximum of 12 doses of 1.5 million IU over a period not to exceed 27 days.

If you are injecting **INTRON A** yourself, please be sure that the dose that has been prescribed for you is clearly provided with the package of medicine you receive. Dosages that are to be administered 3 times a week are best given every other day.

The usual starting dose for each condition follows; however, individual doses may vary, and the doctor may change your dose based on your specific needs:

Chronic hepatitis B: 5 to 10 million IU 3 times a week (every other day) injected subcutaneously (under the skin).

Chronic hepatitis C: 3 million IU 3 times a week (every other day) injected subcutaneously (under the skin) in combination with ribavirin or alone.

Hairy Cell Leukaemia: 2 million IU/m^2, 3 times a week (every other day) injected subcutaneously (under the skin).

Chronic Myelogenous Leukaemia: 4-5 million IU/m^2 daily injected subcutaneously (under the skin).

Non-Hodgkin's Lymphoma (Follicular lymphoma): Adjunctively with chemotherapy, 5 million IU 3 times a week (every other day) injected subcutaneously (under the skin).

Malignant melanoma, induction therapy: 20 million IU/m^2, administered intravenously, given daily for 5 days a week for a 4 week period. Maintenance treatment: 10 million IU/m^2, 3 times a week (every other day) injected subcutaneously (under the skin).

AIDS-Related Kaposi's Sarcoma: Efficacy has been demonstrated at a daily dose of 10 million IU administered subcutaneously. The minimum effective dose is not established. The maximum tolerated daily dose of **INTRON A** is 20 million IU.

Metastatic Renal Cell Carcinoma: As monotherapy: **INTRON A** has been administered subcutaneously at doses ranging from 3 to 30 million IU/m^2 either three times a week, five days per week, or daily.
In combination with other therapeutic agents, such as interleukin-2: **INTRON A** has been administered subcutaneously at doses ranging from 3 to 20 million IU/m^2 in combination with interleukin-2.

Your doctor may prescribe a different dose of **INTRON A** alone or in combination with other medicines (e.g., cytarabine, ribavirin). If you are prescribed **INTRON A** in combination with another medicine, please refer also to the Package Leaflet of the medicine to be used in combination. Your doctor will determine the exact dosage schedule and regimen according to your needs. If you have the impression that the effect of **INTRON A** is too strong or too weak, talk to your doctor or pharmacist.

Subcutaneous use:
INTRON A is usually intended for subcutaneous use. This means that **INTRON A** is injected with a short needle into the fatty tissue just under the skin. If you are injecting this medicine yourself, you will be instructed how to prepare and give the injection. Detailed instructions for subcutaneous administration are provided with this leaflet (see section “HOW TO SELF INJECT **INTRON A**” at the end of the leaflet).

One dose of **INTRON A** is given on each scheduled day. **INTRON A** is given either daily (5 or 7 times a week), or three times a week, every other day, for example on Monday, Wednesday, and Friday.
Interferons may cause unusual tiredness; if you are injecting this medicine yourself, use it at bedtime.

Use **INTRON A** exactly as prescribed by your doctor. Do not exceed the recommended dosage, and take **INTRON A** for as long as prescribed.

If you use more INTRON A than you should
Contact your doctor or healthcare professional as soon as possible.
If you have taken an overdose, or if a child has accidentally swallowed the medicine, proceed immediately to a hospital emergency room and bring the package of the medicine with you.

If you forget to use INTRON A
If you are self-administering treatment, inject the recommended dose as soon as you remember and continue treatment as usual. Do not take a double dose to make up for a forgotten dose. If you are scheduled to inject this medicine every day, and you accidentally missed a full day's dose, continue treatment at the usual dose the following day. Contact your doctor or pharmacist if needed.
Complete the full course of treatment as instructed by the doctor.
Even if there is an improvement in your health, do not discontinue use of this medicine before consulting your doctor.

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 your medicine. Wear glasses if you need them.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. SIDE EFFECTS

Like all medicines, **INTRON A** can cause side effects, in some of the users.
Do not be alarmed by reading the list of side effects, you may not suffer from any of them.
Although not all of these side effects may occur, they may need medical attention if they do.

Psychiatric and central nervous system:
Some people get depressed when taking **INTRON A** alone or in combination treatment with ribavirin, and in some cases people had thoughts about threatening the life of others, suicidal thoughts or aggressive behaviour (sometimes directed against others). Some patients have actually committed suicide. Be sure to seek emergency care if you notice that you are becoming depressed or have suicidal thoughts or change in your behaviour. You may want to consider asking a family member or close friend to help you stay alert to signs of depression or changes in your behaviour.

If any of the following side effects happen, stop taking **INTRON A** and tell your doctor immediately or go to the casualty department at your nearest hospital:
- swelling of the hands, feet, ankles, face, lips, mouth, or throat which may cause difficulty in swallowing or breathing; hives; fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **INTRON A**. You may need urgent medical attention or hospitalisation. These very serious side effects are very rare.

Check with your doctor immediately if any of the following side effects occur:
- chest pain or persistent and severe cough; irregular or rapid heartbeat; shortness of breath, confusion, difficulty remaining alert, numbness or tingling sensation or pain in hands or feet; seizure (convulsions); trouble sleeping, thinking or concentrating; altered mental state; suicidal thoughts, suicide attempt, changed behaviour or aggressive behaviour (sometimes directed against others), hallucinations; severe stomach pain; black or tar like stools; blood in stool or urine, severe nosebleed; pallor, high sugar level in blood, fever or chills beginning after a few weeks of treatment, lower back or side pain, difficult urination, problems with your eyes or your eyesight or hearing, loss of hearing, severe or painful reddening or sores on your skin or mucous membrane.

These may signal serious side effects that may need urgent medical attention. Your doctor will test your blood to ensure that your white blood cell (cells that fight infection) and red blood cell (cells that carry iron and oxygen) counts, platelets (blood clotting cells) and other laboratory values are at acceptable levels. Moderate and usually reversible reduction in all three blood elements-white blood cells, red blood cells and platelets, has been reported.

At the beginning of treatment with **INTRON A**, you may experience a flu-like reaction, with fever, fatigue, headache, muscle ache, joint pain and chills/rigors. Your doctor may recommend that you take paracetamol if you develop these symptoms.

Possible side effects listed below are grouped by frequency of occurrence:
Very common (affects more than 1 user in 10)
Common (affects 1 to 10 users in 100)
Uncommon (affects 1 to 10 users in 1,000)
Rare (affects 1 to 10 users in 10,000)
Very rare (affects less than 1 user in 10,000)
Not known (frequency cannot be estimated from the available data)

The following side effects have been reported:

Very commonly reported side effects:
pain, swelling and redness or skin damage at site of injection, hair loss, dizziness, changes in appetite, stomach or abdominal pains, diarrhoea, nausea (feeling sick), viral infection, depression, emotional lability, insomnia, anxiety, sore throat and painful swallowing, fatigue, chills/rigors, fever, flu-like reaction, feeling of general discomfort, headaches, weight loss, vomiting, irritability, weakness, mood swings, coughing (sometimes severe), shortness of breath, itching, dry skin, rash, sudden and severe muscle pain, joint pain, musculoskeletal pain, changes in laboratory blood values including decreased white blood cell count.

Commonly reported side effects:
thirst, dehydration, high blood pressure, migraines, swollen glands, flushing, menstrual problems, decreased sexual drive, vaginal problem, breast pain, pain in testicle, problems with thyroid gland, red gums, dry mouth, red or sore mouth or tongue, tooth ache or tooth disorder, herpes simplex (fever blisters), taste change, upset stomach, dyspepsia (heartburn), constipation, enlargement of liver (liver problems, sometimes severe), loose stools, inflammation of the sinuses, bronchitis, eye pain, problem with your tear ducts, conjunctivitis (“pink eye”), agitation, sleepiness, sleepwalking, problem with behaviour, nervousness, stuffy or runny nose, sneezing, rapid breathing, pale or reddened skin, bruising, problem with skin or nails, psoriasis (new or worsened), increased sweating, increased need to pass urine, fine shaking movements, decreased sensitivity to touch, arthritis.

Uncommonly reported side effects:
bacterial infection, feeling of pins and needles, and pericarditis (inflammation of the lining of the heart).

Rarely reported side effects:
pneumonia.

Very rarely reported side effects:
low blood pressure, puffy face, diabetes, leg cramps, back pain, kidney problems, nerve damage, bleeding gums, aplastic anaemia. Pure red cell aplasia, a condition where the body stopped or reduced the production of red blood cells, has been reported. This causes severe anaemia, symptoms of which would include unusual tiredness and a lack of energy.
Very rarely sarcoidosis, (a disease characterised by persistent fever, weight loss, joint pain and swelling, skin lesions and swollen glands) has been reported. Loss of consciousness has occurred very rarely,

mostly in elderly patients treated at high doses. Cases of stroke (cerebrovascular events) have been reported. Check with your doctor immediately if you have any of these symptoms.

Not known side effects:
Periodontal (affecting gums) and dental disorders, change in colour of the tongue, altered mental status, loss of consciousness, acute hypersensitivity reactions including urticaria (hives), angioedema (swelling of the hands, feet, ankles, face, lips, mouth, or throat which may cause difficulty in swallowing or breathing), bronchoconstriction and anaphylaxis (a severe, whole-body allergic reaction) have been reported, but their frequency is unknown.
Additionally, Vogt-Koyanagi-Harada syndrome (an autoimmune inflammatory disorder affecting the eyes, skin and the membranes of the ears, brain and spinal cord), thoughts about threatening the life of others, mania (excessive or unreasonable enthusiasm), bipolar disorders (mood disorders characterized by alternating episodes of sadness and excitement), congestive heart failure, pericardial effusion (a fluid collection that develops between the pericardium (the lining of the heart) and the heart itself), pulmonary fibrosis (scarring of the lungs), and hepatitis B reactivation in HCV/HBV co-infected patients (recurrence of hepatitis B disease) have been reported with **INTRON A** use.

Pulmonary arterial hypertension – a disease of severe narrowing of the blood vessels in the lungs resulting in high blood pressure in the blood vessels that carry blood from the heart to the lungs. This may occur in particular in patients with risk factors such as HIV infection or severe liver problems (cirrhosis). The side effect may develop at various time points during treatment, typically several months after starting treatment with **INTRON A**.

If a side effect appears, if any of the side effects gets serious or if you notice any side effect not mentioned in this leaflet, consult your doctor.

Reporting of side effects
Side effects can be reported to the Ministry of Health by using the online form for adverse events reporting which is on the Ministry of Health Homepage: www.health.gov.il
or by following the link:
https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il

5. HOW TO STORE INTRON A?

- Avoid Poisoning! This medicine, as all other medicines, must be stored in a safe place out of the reach and sight of children and/or infants, in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor!
- Do not use **INTRON A** after the expiry date (exp. date) which is stated on the pack. The expiry date refers to the last day of the indicated month.
- **Storage conditions**: Store in a refrigerator **(**2°C-8°C).
  Do not freeze.
  Return to refrigerator after each use. Each pen is intended for a maximum 27 days use period and must then be discarded. A maximum of 48 hours (two days) of exposure to 25°C is permitted over the 27 days period to cover accidental delays in returning the pen to the refrigerator.
- Do not use this medicine if you notice changes in the appearance of **INTRON A**.
- Depending upon your dose, you may have extra needles and swabs left in the pack. Please discard these appropriately and safely.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

6.1 What INTRON A contains

- The active substance is recombinant interferon alfa-2b. Each pen contains 18 million IU.

- In addition to the active ingredient the medicine also contains inactive ingredients: Sodium chloride, Sodium phosphate dibasic anhydrous, m-cresol, Sodium phosphate monobasic monohydrate, Edetate disodium, Polysorbate 80, Water for injection.

6.2 What INTRON A looks like and contents of the pack
INTRON A is presented as a solution for injection in a multidose pen.
The clear and colourless solution is contained in a glass cartridge.
INTRON A is available in the following pack size:
Pack of 1 pen, 6 injection needles and 6 cleansing swabs.

6.3 License Holder
Merck Sharp & Dohme (Israel-1996) Company Ltd., P.O.Box 7121, Petah-Tikva 49170.

6.4 Manufacturer
Merck Sharp & Dohme Corp., NJ, USA.

This Leaflet was checked and approved by the Ministry of Health in June 2016.

Drug registration no. listed in the official registry of the Ministry of Health
117.72.29898.00

HOW TO SELF INJECT INTRON A

The following instructions explain how to inject **INTRON A** yourself. Please read the instructions carefully and follow them step by step. Your doctor or his/her assistant will instruct you how to self-inject **INTRON A**. Do not attempt to inject yourself unless you are sure you understand the procedure and requirement of self-injection.

Preparation
Collect necessary items before you begin:
- the **INTRON A** multidose pen;
- a needle for subcutaneous injection (provided in the packaging);
- a cleansing swab (provided in the packaging).

Wash your hands carefully. Use the injection needles provided in the packaging only for **INTRON A**. Use a new injection needle for each dose. Be sure the solution is at room temperature (up to 25°C) at the time of injection.

Diagrams 1 and 2 show you all the different parts of the pen and the injection needle. The most important parts to note are as follows:
- The push button scale tells you what dose has been set.
- The colour coding strip brown and the push button are at the bottom of the pen as it is held cap up.
- The pen can only be fully capped when the triangle on the cap scale is aligned with the dosage indicator on the barrel.

Measuring the dose of **INTRON A**
Take the pen out of the refrigerator about one-half hour before administering the dose so that the solution in the pen is at room temperature when it is injected.
When you are ready to give your injection prepare your pen as follows:
Check that **INTRON A** solution for injection is clear and colourless in appearance prior to use. If it does not have a clear uniform appearance or if it contains any particles, do not use.
Pull off the cap of the pen and disinfect the rubber membrane (see Diagram 3) with one cleansing swab.

Remove the protective tab from the injection needle. Note that the rear portion of the injection needle is revealed once the protective tab is removed (see Diagram 4).

Gently push the injection needle onto the pen as shown in Diagram 5. (Notice that the rear portion of the injection needle will pierce through the rubber membrane that you disinfected previously). Now screw the injection needle onto the pen securely by turning it in a clockwise direction (see Diagram 6).

First, pull off the outer injection needle cap (Diagram 7). Then, pull off the inner injection needle cap carefully, bearing in mind that the injection needle will now be exposed (Diagram 8). Keep the outer injection needle cap for later use.

The pen is now ready to use. Since a small amount of air may collect in the injection needle and reservoir during storage, the next step is to remove any air bubbles. This is called performing the Air-Shot.
Hold the pen with the injection needle point upwards.
Tap the reservoir with your finger so that any air bubbles rise to the top of the reservoir, just below the injection needle (Diagram 9).

Hold the pen by the barrel and turn the reservoir in the direction as indicated by the arrow in Diagram 10 (clockwise) until you feel it click.

Keeping the pen pointing upwards, press the push button up fully and see if a drop of solution appears at the injection needle tip (Notice the drop at the tip of injection needle in Diagram 11 below).

If no drop appears, use a different pen, and return the faulty pen to your provider.
Note: some air may remain in the pen, but this is not important as you have removed the air from the injection needle and the dose will be accurate.
Replace the pen cap with the ‘triangle’ opposite the dosage indicator as seen in Diagram 12.

The pen is now ready to set the dose. For the next step hold the pen in the middle of the barrel. This will allow the push button to move freely, ensuring that the correct dose is set.
To set the required dose, hold the pen horizontally by the barrel with one hand. With the other hand, turn the cap in a clockwise direction indicated by the arrow in Diagram 13. You will observe the push button rising, indicating the dose set. To set the correct dose, turn the cap as many times as indicated as follows:

Number of "turns" and "clicks"	Corresponding doses (million IU) using IntronA, solution for injection, multidose pen 18 million IU/pen
1 full turn (5 clicks)	1.5
6 clicks	1.8
7 clicks	2.1
8 clicks	2.4
9 clicks	2.7
2 full turns (10 clicks)	3
11 clicks	3.3
12 clicks	3.6
13 clicks	3.9
14 clicks	4.2
3 full turns (15 clicks)	4.5
16 clicks	4.8
17 clicks	5.1
18 clicks	5.4
19 clicks	5.7
4 full turns (20 clicks)*	6

*4 full turns correspond to the maximum dose to be administered in one injection. The pen is designed to deliver its contents of 18 million IU in doses ranging from 1.5 to 6 million IU. The pen will deliver a maximum of 12 doses of 1.5 million IU over a period not to exceed 27 days.

The push button scale will show you the dose set (see Diagram 14 below). For doses corresponding to full turns, the scale should line up with the correct dose marking. For doses corresponding to clicks intermediate between full turns, the scale should line up between the two appropriate full-turn dose markings. At that point check that you have the correct dose.

After each complete turn make sure that the triangle is opposite the dosage indicator (see Diagram 15).
If you have set a wrong dose, simply turn the cap back (anti-clockwise) as far as you can until the push button is fully home and start again. Once the correct dose is set you are ready to give the injection.

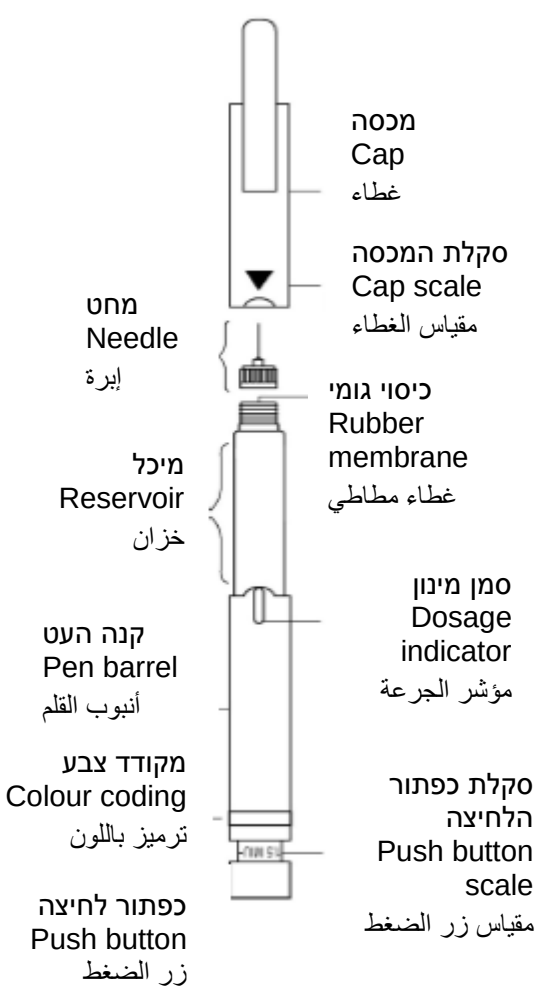
Injecting the solution

Select the injection site. The best sites for injection are tissues with a layer of fat between skin and muscle: thigh, outer surface of the upper arm (you may need the assistance of another person to use this site), abdomen (except the navel or waistline). If you are exceptionally thin, use only the thigh or outer surface of the arm for injection. Change your injection site each time.
Cleanse and disinfect the skin where the injection is to be made. Wait for the area to dry.
With one hand, pinch a fold of loose skin. With your other hand, pick up the pen and hold it as you would a pencil. Insert the needle into the pinched skin at an angle of approximately 45°.
Then press the push button down fully (see Diagram 16).

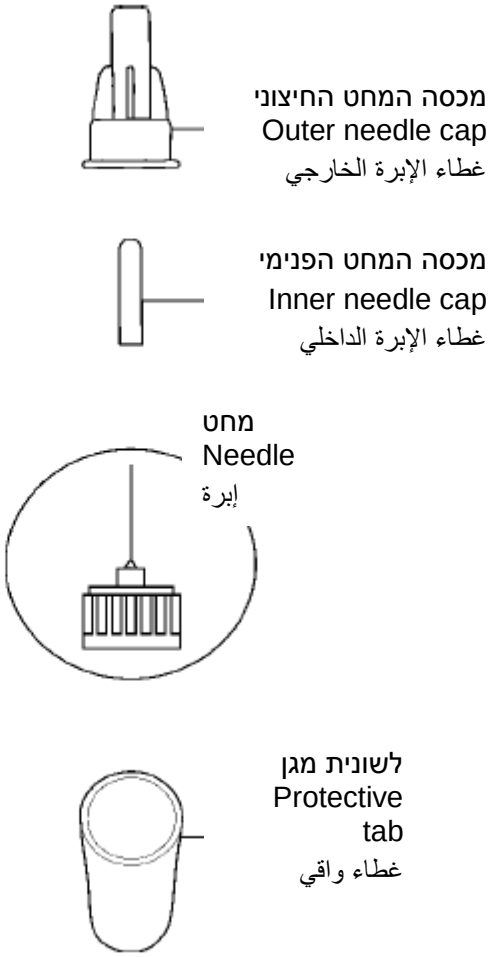
Keeping the push button down, leave the injection needle in place for a few seconds to allow the solution to distribute under the skin, then remove.
Carefully replace the outer injection needle cap (see Diagram 17).

Completely unscrew the injection needle assembly using an anti-clockwise turning motion as shown in Diagram18. Then carefully lift it off the pen and discard the capped injection needle (see Diagram 19).

Replace the pen cap with the triangle once again opposite the dosage indicator as shown in Diagram 20. Then return the pen to the refrigerator.



תרשים 1
Diagram 1
الرسم ١

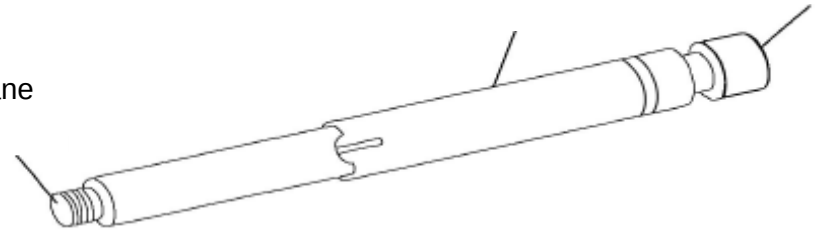


תרשים 2
Diagram 2
الرسم ٢

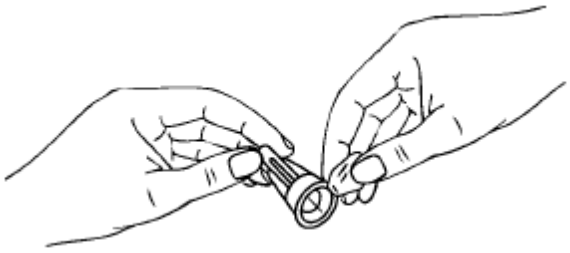
כפתור לחיצה
Push button
زر الضغط

קנה העט
Pen barrel
أنبوب القلم

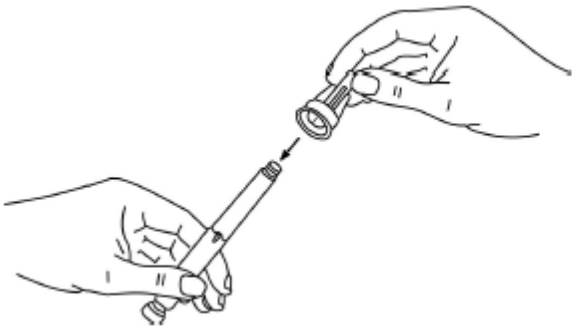
כיסוי גומי
Rubber membrane
غطاء مطاطي



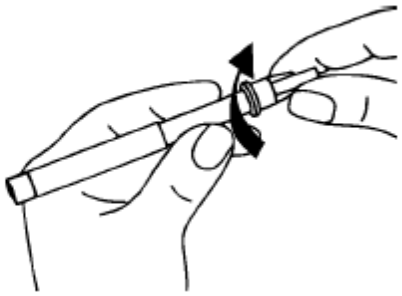
תרשים 3
Diagram 3
الرسم ٣



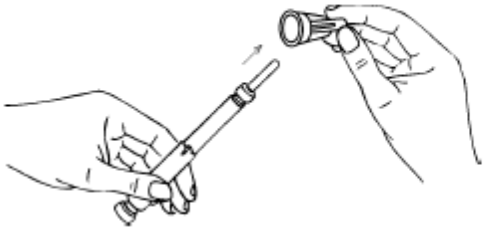
תרשים 4
Diagram 4
الرسم ٤



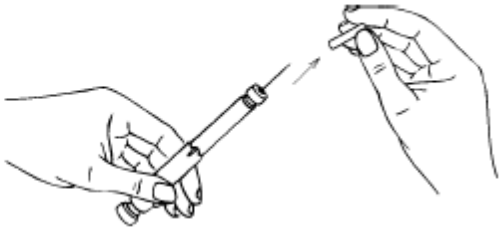
תרשים 5
Diagram 5
الرسم ٥



תרשים 6
Diagram 6
الرسم ٦



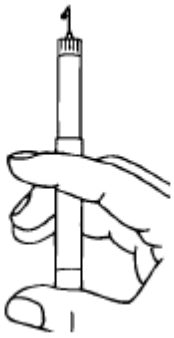
תרשים 7
Diagram 7
الرسم ٧



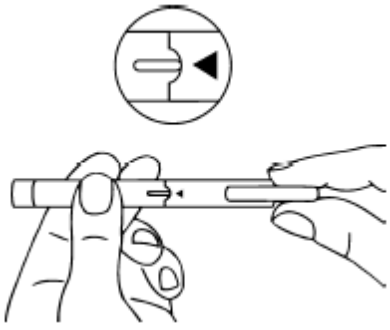
תרשים 8
Diagram 8
الرسم ٨

תרשים 9
Diagram 9
الرسم ٩

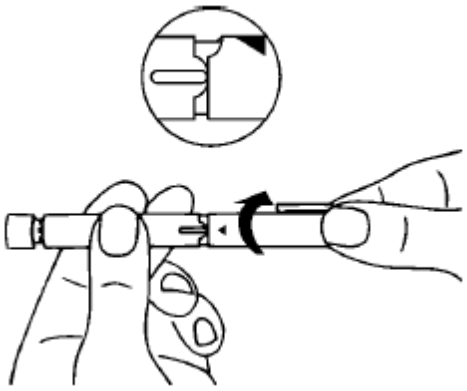
תרשים 10
Diagram 10
الرسم ١٠



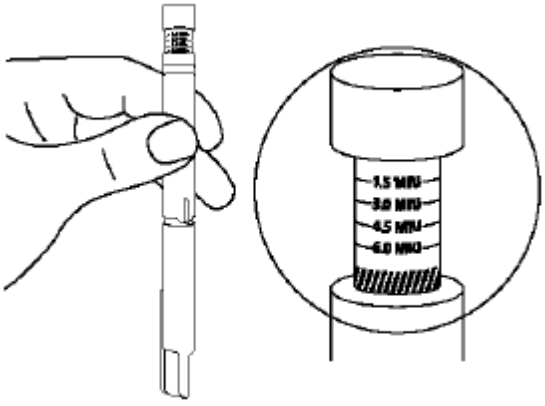
תרשים 11
Diagram 11
الرسم ١١



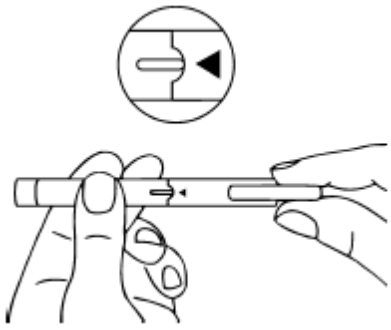
תרשים 12
Diagram 12
الرسم ١٢



תרשים 13
Diagram 13
الرسم ١٣

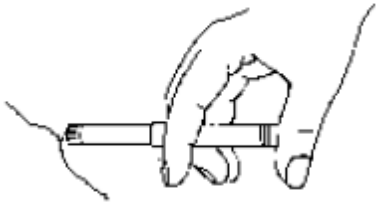


תרשים 14
Diagram 14
الرسم ١٤

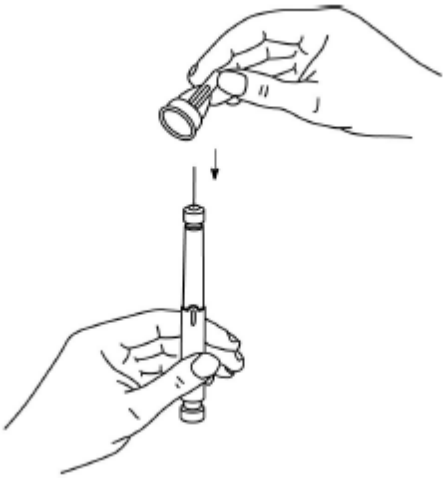


תרשים 15

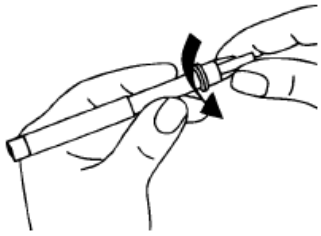
Diagram 15
الرسم ١٥



תרשים 16
Diagram 16
الرسم ١٦

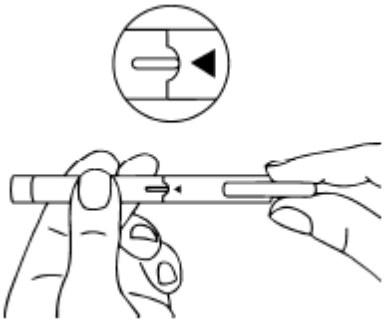


תרשים 17
Diagram 17
الرسم ١٧



תרשים 18
Diagram 18
الرسم ١٨

תרשים 19
Diagram 19
الرسم ١٩



תרשים 20
Diagram 20
الرسم ٢٠