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INJECTION TRAINING BROCHURE PEYRONIE'S DISEASE

THE FOLLOWING TRAINING BROCHURE IS DESIGNED TO ENSURE APPROPRIATE TREATMENT OF PATIENTS WITH PEYRONIE'S DISEASE WITH XIAPEX

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See www.mhra.gov.uk/yellowcard for how to report side effects.

XIAPEX®▼
collagenase clostridium histolyticum

THE FOLLOWING TRAINING BROCHURE IS DESIGNED TO ENSURE APPROPRIATE TREATMENT OF PATIENTS WITH PEYRONIE'S DISEASE WITH XIAPEX AND INCLUDES:

- The risks of penile fracture or other serious injury to the penis
- The steps necessary to prepare and administer Xiapex
- The in-clinic penile modeling procedure that is part of each Xiapex treatment cycle
- The daily, at-home penile modeling activities that are performed by the patient for approximately 6 weeks after each treatment cycle
- Counselling your patient

CONTENTS

BACKGROUND

PEYRONIE'S DISEASE

Peyronie's disease is a localized connective tissue disorder characterized by changes in collagen composition in the tunica albuginea.[1] These changes cause an abnormal scar formation known as Peyronie's plaque, which is typically a palpable bump under the skin.[2–4]

The Peyronie's plaque is composed predominantly of collagen, and replaces the normally elastic fibers of the tunica albuginea. Microvascular trauma resulting from bending or injury to the penis (possibly during sexual activity) is thought to be an important trigger for the inflammatory response and plaque development characteristic of Peyronie's disease. Genetic predisposition and autoimmunity may also play a role in its development.

The Peyronie's plaque prevents the normal stretching of the penis during erection and may result in one of the hallmarks of Peyronie's disease, penile curvature deformity. This curvature deformity may cause significant bother / distress. Peyronie's disease may also cause other types of deformities, including narrowing, indentation, and shortening of the penis.

INDICATION

Xiapex is indicated for the treatment of adult men with Peyronie's disease with a palpable plaque and curvature deformity of at least 30 degrees at the start of therapy. Xiapex should be administered by a physician appropriately trained in the correct administration of the product and experienced in the diagnosis and treatment of male urological diseases.

Xiapex is also indicated for the treatment of adult patients with Dupuytren's contracture with a palpable cord. It should be administered by physicians appropriately trained in the correct administration of the product and experienced in the diagnosis and management of Dupuytren's disease.[5]

Xiapex contains 2 different types of purified collagenase clostridium histolyticum (AUX-I and AUX-II), in a defined mass ratio. Injection of Xiapex into a Peyronie's plaque, which is composed mostly of collagen, may result in enzymatic disruption of the collagen found in Peyronie's plaque. Following this disruption of the collagen-containing plaque, penile curvature deformity may improve while Patient-Reported Bother may be reduced.

XIAPEX TREATMENT OVERVIEW

- Xiapex, supplied as a lyophilized powder, **must be reconstituted with the provided diluent prior to use.**
- The dose of Xiapex is 0.58 mg per injection administered into a Peyronie's plaque. If more than one plaque is present, inject into the plaque causing the curvature deformity.
- A treatment course consists of a maximum of 4 treatment cycles. Each treatment cycle consists of 2 Xiapex injection procedures and one in-clinic penile modeling procedure. The second Xiapex injection procedure occurs 1 to 3 days after the first. The in-clinic penile modeling procedure is performed 1 to 3 days after the second injection of the treatment cycle (see picture below). It is necessary to identify the treatment area prior to each treatment cycle.
- Healthcare providers must counsel patients on:
  - the risks of penile fractures or other serious injuries of the penis
  - how to perform the at-home penile modeling activities as appropriate
- After the third clinic visit of each treatment cycle, the patient performs approximately 6 weeks of daily, at-home penile modeling activities.
- Up to 4 treatment cycles (for a total of 8 injection procedures and 4 modeling procedures) may be administered per plaque causing the curvature deformity. If the curvature deformity is less than 15 degrees after the first, second or third treatment cycle, or if the healthcare provider determines that further treatment is not clinically indicated, then the subsequent treatment cycles should not be administered.
- The safety of more than one treatment course of Xiapex (comprising 4 treatment cycles) is not known.

PREPARING FOR ADMINISTRATION

This section summarizes the procedure for reconstituting the lyophilized powder of Xiapex. Xiapex is supplied in single-use glass vials containing 0.9 mg of collagenase clostridium histolyticum as a sterile, lyophilized powder for reconstitution. Sterile diluent for reconstitution is supplied in the package in a single-use glass vial containing 3 ml of 0.3 mg/ml calcium chloride dihydrate in 0.9 % sodium chloride. **Xiapex must be reconstituted with the provided diluent prior to use.**

PRIOR TO RECONSTITUTION

Store in refrigerator

Prior to reconstitution, the vials of lyophilized powder of Xiapex and sterile diluent should be stored in a refrigerator at 2°C to 8°C. Do not freeze.

BEFORE USE

1. Remove the vial containing the lyophilized powder of Xiapex and the vial containing the diluent for reconstitution from the refrigerator and check the labels on both the diluent vial and the lyophilized powder vial to make sure they have not expired. Allow the 2 vials to stand at room temperature for at least 15 minutes but no longer than 60 minutes.

BEFORE RECONSTITUTION

Remove vials from refrigerator and let stand at room temperature for 15-60 minutes

2. Visually inspect the vial containing Xiapex. The cake of lyophilized powder should be intact and white in color. If the cake has been eroded, it should not be used and should be reported to Swedish Orphan Biovitrum: complaints@sobi.com.

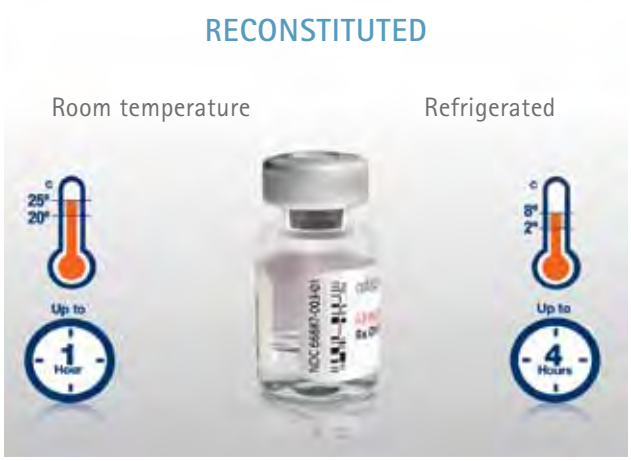
3. After removing the flip-off cap from each vial, using aseptic technique swab the rubber stopper and surrounding surface of the vial containing Xiapex and the vial containing the diluent for reconstitution with sterile alcohol (no other antiseptics should be used). Use only the supplied diluent for reconstitution. The diluent contains calcium, which is required for the activity of Xiapex.
4. Using a 1-ml syringe with 0.01-ml graduations with a 26 or 27-gauge, 12 or 13 mm needle (not supplied), withdraw a volume of 0.39 ml of the **diluent supplied.**

5. Inject the diluent slowly into the sides of the vial containing the lyophilized powder of Xiapex.

6. Do not invert the vial or shake the solution. Slowly swirl the solution to ensure that all of the lyophilized powder has gone into the solution. Do not use if opaque particles, discoloration, or other foreign particles are present.

7. The reconstituted Xiapex solution is now ready for injection.

8. The reconstituted Xiapex solution can be kept at room temperature 20°C to 25°C for up to 1 hour or refrigerated at 2°C to 8°C for up to 4 hours prior to administration. If the reconstituted Xiapex solution is refrigerated, allow the solution to return to room temperature for approximately 15 minutes before use and no longer than 60 minutes.



9. Do not recap the needle. Discard the syringe, needle, and diluent used for reconstitution using medical waste disposal procedures.

IDENTIFYING THE TREATMENT AREA AND INJECTING XIAPEX

This section outlines the procedures for identifying the treatment area and injecting the reconstituted Xiapex solution into the Peyronie's plaque. Care should be taken to avoid injury to the urethra. Do not inject Xiapex in patients with ventral curvature deformity, including hourglass deformities engaging the ventral aspect of the penis.

NOTE: Prior to administering Xiapex and as part of every treatment-related visit, use the Patient Package Leaflet to discuss important information with each patient. Patients should be given the Patient Package Leaflet to take home for reference.

IDENTIFYING THE TREATMENT AREA

Prior to each treatment cycle, identify the treatment area as follows:

1. Induce a penile erection. A single intracavernosal injection of 10 or 20 micrograms of alprostadil may be used for this purpose. Apply antiseptic at the site of injection and allow the skin to dry prior to the intracavernosal injection.
2. Locate the plaque at the point of maximum concavity (or focal point) in the bend of the penis.

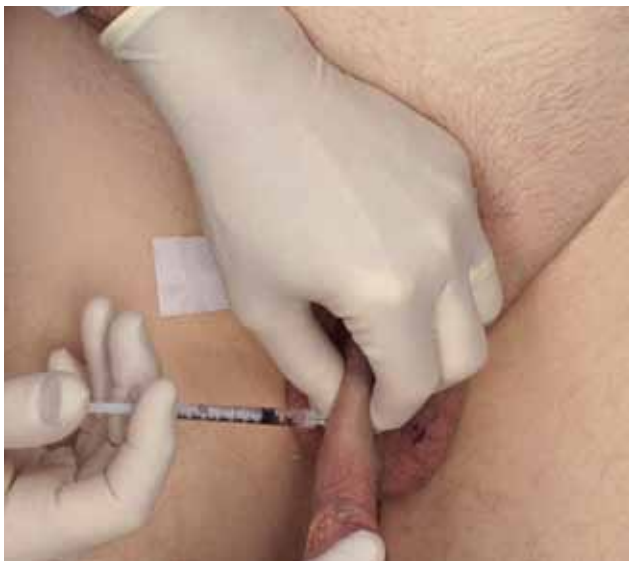
3. Mark the point with a surgical marker. This indicates the target area in the plaque for Xiapex deposition.

4. The penis should be in a flaccid state before Xiapex is injected.

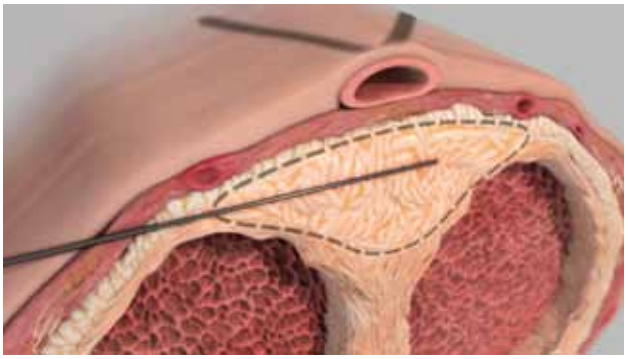
INJECTION PROCEDURE

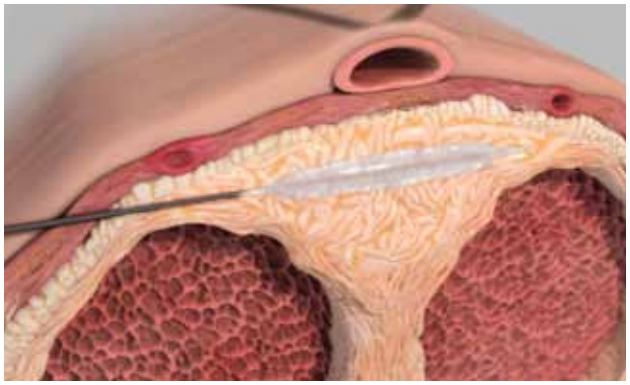
The reconstituted Xiapex solution should be clear. Inspect the solution visually for particulate matter and discoloration prior to administration. If the solution contains particulates, is cloudy, or is discolored, do not inject the reconstituted solution.

1. Apply antiseptic at the site of the injection and allow the skin to dry. Administer suitable local anesthetic, if desired.
2. Using a new hubless syringe containing 0.01-ml graduations with a permanently fixed 27-gauge 12 or 13 mm needle (not supplied), withdraw a volume of 0.25 ml of **reconstituted solution (containing 0.58 mg of Xiapex).** There will be a small amount of reconstituted solution left in the vial.
3. The penis should be in a flaccid state before Xiapex is injected. Place the needle tip on the side of the target plaque in alignment with the point of maximal concavity. Orient the needle so that it enters the plaque from the side, NOT downwards or perpendicularly towards the corpora cavernosum.



4. Insert and advance the needle transversely through the width of the plaque, towards the opposite side of the plaque without passing completely through it. Proper needle position is confirmed by carefully noting resistance to minimal depression of the syringe plunger.





5. With the tip of the needle placed within the plaque, initiate the injection, maintaining steady pressure to slowly inject the drug into the plaque. Withdraw the needle slowly, so as to deposit the full dose along the needle track within the plaque. For plaques that are only a few millimeters in width, the distance of withdrawal of the syringe may be very minimal. The goal is always to deposit the full dose entirely within the plaque.

6. Upon complete withdrawal of the needle, apply gentle pressure at the injection site. Apply a dressing as necessary.

7. Discard the unused portion of the reconstituted solution and diluent after each injection. Do not store, pool, or use any vials containing unused reconstituted solution or diluent.

8. The second injection of each treatment cycle should be made approximately 2 mm to 3 mm apart from the first injection and within the plaque.

INFORMATION TO SHARE WITH PATIENTS

At each patient visit, counsel the patient as appropriate on the following:

- The risks of penile fracture and other serious injury to the penis.
- That their penis may appear bruised and/or swollen.
- That they may have mild-to-moderate penile pain that can be relieved by taking over-the-counter pain medications.
- To promptly contact their physician if, at any time, they have any of these symptoms:
  - a popping sound or sensation in an erect penis
  - sudden loss of the ability to maintain an erection
  - severe purple bruising and swelling of the penis
  - difficulty urinating or blood in the urine
  - severe pain in the penis

These symptoms may indicate penile fracture, and may require surgery.

- To return to their healthcare provider's clinic when directed for further injection(s) and/or penile modeling procedure(s).
- **To not have sex or engage in any sexual activity after the first injection and for at least 2 weeks after the second injection in each treatment cycle, provided any pain and swelling has gone away.**

ADDITIONAL POTENTIAL RISKS

Following Xiapex injection, severe allergic reaction could occur, and patients should be observed for 30 minutes before leaving the clinic in order to monitor for any signs or symptoms of a serious allergic reaction, e.g. wide spread redness or rash, swelling, tightness in the throat or difficulty breathing. Patients should be instructed to consult a doctor immediately if they experience any of these signs or symptoms.

Emergency medication for treatment of potential allergic reactions should be available.

There is also a theoretical risk of reactions related to cross-reactivity with endogenous human matrix metalloproteinases (MMPs) (including the development of a musculo-skeletal syndrome and the development or exacerbation of autoimmune disorders) although clinical evidence of this has not been observed.

Xiapex must be used with caution in patients with coagulation disorders or those taking anticoagulants. Use of Xiapex in patients who have received anticoagulants (with the exception of up to 150 mg acetylsalicylic acid daily) within 7 days prior to receiving an injection of Xiapex is not recommended.

PENILE MODELING (IN-CLINIC AND AT-HOME)

This section outlines the in-clinic penile modeling procedure, which, in conjunction with Xiapex, helps relieve curvature deformity and straighten the penile shaft. At a follow-up visit 1 to 3 days after the second injection of each treatment cycle, perform a penile modeling procedure (as described below) on the flaccid penis to stretch and elongate the treated plaque.

This section also outlines instructions to give to patients on how to perform daily, at-home penile modeling activities for 5 to 6 weeks following each treatment cycle.

NOTE: Prior to administering Xiapex and as part of every treatment-related visit, make sure to counsel each patient and discuss important information.

Dorsal plaque being modeled

IN-CLINIC PENILE MODELING PROCEDURE

1. Administer suitable local anesthetic, if desired.
2. Wearing gloves, grasp the plaque or indurated portion of the flaccid penis about 1 cm proximal and distal to the injection site. Avoid direct pressure on the injection site.
3. Using the target plaque as a fulcrum point, use both hands to apply firm, steady pressure to elongate and stretch the plaque. The goal is to gradually create bending opposite to the patient's penile curvature, with stretching to the point of moderate resistance.
4. Hold pressure for 30 seconds, then release.
5. After a 30-second rest period, repeat the penile modeling technique for a total of 3 modeling attempts at 30 seconds for each attempt.

PENILE MODELING (IN-CLINIC AND AT-HOME) (continued)

AT-HOME PENILE MODELING ACTIVITIES

There are 2 types of at-home penile modeling activities. One is a gentle stretching activity; the other is a gentle straightening activity. Discuss with patients the best time to perform these activities. Patients will do these for approximately 6 weeks after each treatment cycle.

Side view of penis stretching activity to be performed **three times per day.**

Top view of penis straightening activity to be performed **no more than once per day,** if a spontaneous erection unrelated to sexual activity occurs.

For the **stretching** activity, instruct the patient to:

1. Grasp the tip of the penis with the fingers of one hand and hold the base of the penis with the fingers of the other.
2. **Gently** pull the penis away from the body to its full length.
3. Hold the stretch for 30 seconds.
4. Let go and allow the penis to return to its normal, unstretched length.

Patients should perform the penis-stretching activity daily, three times per day, with a nonerect penis.

For the **straightening** activity, instruct the patient to:

1. **Gently** attempt to bend the shaft of the erect penis in the opposite direction of the curve, but not so forcefully as to produce significant pain or discomfort.
2. Hold the penis in this more straightened position for 30 seconds, then let go.
3. Perform this no more than once per day, if a spontaneous erection unrelated to sexual activity occurs.

Patients should perform the penis-straightening activity no more than once per day only if a spontaneous erection occurs. If the patient does not have a spontaneous erection, he should not attempt the penis straightening.

PACKAGE LEAFLET AND PATIENT COUNSELLING

PACKAGE LEAFLET

The Patient Package Leaflet included in the package, must be given to the patient at each visit to take home. The Patient Package Leaflet contains the following information that you should discuss with each patient:

- The risks of corporal rupture (penile fracture) and other serious penile injury.
- Precautions related to the patient's actions to reduce these adverse outcomes (eg, advising patients to not engage in any kind of sexual activity for at least 2 weeks after any Xiapex injection, and any pain and swelling have gone away, before resuming sexual activity).
- Symptoms to look for and conditions under which patients should promptly contact their healthcare provider.
- Clear instructions on at-home penile modeling activities.

If needed, additional package leaflets can be ordered on the Xiapex website or by contacting Sobi:

www.xiapex.eu
medical.info@sobi.com

PATIENT COUNSELLING

WHAT YOUR PATIENT NEED TO KNOW ABOUT XIAPEX TREATMENT FOR PEYRONIE'S DISEASE

The patients should keep the Patient Package Leaflet for important safety information and instructions for his at-home activities.

Review this counselling guide with your patients and give them a copy of the Patient Package Leaflet from the package. The information in this guide highlights the most important risks and instructions to patients in accordance with the Patient Package Leaflet and it's important to ensure that patients clearly understand the instructions.

WHAT ARE THE SERIOUS RISKS OF XIAPEX TREATMENT?

The patient should be informed that Xiapex can cause serious side effects including Penile fracture (corporal rupture) or other serious injury to the penis, such as hematoma.

The patient should be informed that he could not engage in any kind of sexual activity for at least 2 weeks after any Xiapex injection, and the pain and swelling have gone away, or until given permission by you as his healthcare provider.

WHAT SYMPTOMS DOES THE PATIENT NEED TO LOOK FOR?

The patient should be informed that he should call you as his healthcare provider right away if any of the following symptoms of penile fracture or other serious injury to the penis occur:

- A popping sound or sensation in an erect penis
- Sudden loss of the ability to maintain an erection
- Severe purple bruising and swelling of the penis
- Difficulty urinating or blood in the urine
- Severe pain in the penis

The patient should be informed that he may report side effects to the Health Authority via the national reporting system or to the Swedish Orphan Biovitrum Drug Information Center: medical.info@sobi.com.

HOW CAN THE PATIENT LOWER THE RISKS ASSOCIATED WITH XIAPEX?

Before treatment:

The patient should be informed that he should:

- Tell you, as his healthcare provider, if he has ever had an allergic reaction to Xiapex.
- Tell you, as his healthcare provider, about all the medications he takes, especially anticoagulation medicines. The patient should not receive Xiapex within 7 days of last dose of anticoagulation medicine, with the exception of up to 150 mg daily doses of acetylsalicylic acid.
- Tell you, as his healthcare provider, if he has any coagulation problems or other medical conditions.

After treatment:

The patient should be informed that:

- Within 24 hours after treatment, his penis may appear bruised and/or swollen and he may have mild-to-moderate penile pain. He should ask you as his healthcare provider if over-the-counter medications are appropriate.
- He should not engage in sexual activity for at least 2 weeks following any injection of Xiapex, and the pain and swelling has gone away, or until given permission by you as his healthcare provider.
- He should do gentle stretching and straightening of his penis at home as shown on the next page.
- Return to you as his healthcare provider when directed, for further injection(s) and/or penile modeling procedures.

PATIENT COUNSELLING (continued)

WHAT DOES THE PATIENT HAVE TO DO AT HOME?

The patient should be informed that for the 6 weeks after each treatment cycle, he will need to perform the following **gentle penis stretching and straightening** activities. As his doctor you will tell him exactly when to start and how long to continue.

Side view of penis stretching activity

Top view of penis straightening activity

1) PENIS STRETCHING (when penis is **not** erect)

Side view of penis stretching activity

- Grasp the tip of the penis with the fingers of one hand and hold the base of the penis with the fingers of the other hand (see picture above).
- **Gently** pull your penis away from the body to its full length.
- Hold the stretch for 30 seconds.
- Let go and allow the penis to return to its normal, unstretched length.
- Do this stretching **three times** each day, only when the penis is not erect.

2) PENIS STRAIGHTENING (when penis **is** erect)

Top view of penis straightening activity

- During a spontaneous erection, not related to sexual activity, attempt to straighten the penis by **gently** bending the shaft in the opposite direction of the curve, but **not so forcefully so as to produce significant pain or discomfort.**
- Hold the penis in this more straightened position for 30 seconds, then let go (see picture above).
- Do this straightening only **one time** each day. If no spontaneous erection, do not attempt the penis straightening activity.

References: 1. Hellstrom WJ. Medical management of Peyronie's disease. J Androl. 2009;30(4):397-405. **2.** Ralph D, Gonzalez-Cadavid N, Mirone V, et al. The management of Peyronie's disease: evidence-based 2010 guidelines. J Sex Med. 2010;7(7):2359-2374. **3.** Moreland RB, Nehra A. Pathophysiology of Peyronie's disease. Int J Impot Res. 2002;14(5):406-410. **4.** Bella AJ, Perelman MA, Brant WO, Lue TF. Peyronie's disease (CME). J Sex Med. 2007;4(6):1527-1538. **5.** Xiapex SPC January 2015.

ABBREVIATED PRESCRIBING INFORMATION

XIAPEX® Abbreviated Prescribing Information (Peyronie's Disease):

(See XIAPEX Summary of Product Characteristics for full Prescribing Information)

Presentation: Powder and solvent for solution for injection. The vial of powder contains 0.9 mg collagenase *clostridium histolyticum*. The powder is a white lyophilised powder and the solvent is a clear colourless solution.
Indications: The treatment of adult men with Peyronie's disease with a palpable plaque and curvature deformity of at least 30 degrees at the start of therapy.
Dosage: Xiapex must be administered by a physician appropriately trained in the correct administration of the product and experienced in the diagnosis and treatment of male urological diseases. The recommended dose of Xiapex is 0.58 mg per injection administered into a Peyronie's plaque. The volume of reconstituted Xiapex to be administered into the plaque is 0.25 ml. If more than one plaque is present, only the plaque causing the curvature deformity should be injected. A treatment course consists of a maximum of 4 treatment cycles. Each treatment cycle consists of two Xiapex injections and one penile modelling procedure. The second Xiapex injection is administered 1 to 3 days after the first injection. A penile modelling procedure is performed 1 to 3 days after the second injection of each treatment cycle. The interval between treatment cycles is approximately six weeks.
Contraindications: Hypersensitivity to the active substance or to any of the excipients. Treatment of Peyronie's plaques that involve the penile urethra due to potential risk to this structure.
Warnings and Precautions: *Allergic reactions* - Following Xiapex injection, severe allergic reaction could occur, and patients should be observed for 30 minutes before leaving the clinic in order to monitor for any signs or symptoms of a serious allergic reaction, e.g. wide spread redness or rash, swelling, tightness in the throat or difficulty breathing. Patients should be instructed to consult a doctor immediately if they experience any of these signs or symptoms. Emergency medication for treatment of potential allergic reactions should be available. An anaphylactic reaction was reported in a post-marketing clinical study in a patient who had previous exposure to Xiapex for the treatment of Dupuytren's contracture, demonstrating that severe reactions including anaphylaxis can occur following Xiapex injections. *Corporal rupture* was reported as a serious adverse event after Xiapex injection in 5 out of 1044 patients (0.5%) in the controlled and uncontrolled clinical trials in Peyronie's disease. In other Xiapex-treated patients (9 of 1044; 0.9%), a combination of penile ecchymoses or haematoma, sudden penile detumescence, and/or a penile "popping" sound or sensation was reported, and in these cases, a diagnosis of corporal rupture cannot be excluded. Severe penile haematoma was also reported as an adverse reaction in 39 of 1044 patients (3.7%) in the controlled and uncontrolled clinical studies in Peyronie's disease. Signs or symptoms that may reflect serious injury to the penis should be promptly evaluated in order to assess for corporal rupture or severe penile haematoma. *Use in patients with coagulation disorders* – Xiapex must be used in caution in patients with coagulation disorders or those taking anticoagulants. Use of Xiapex in patients who have received anticoagulants (with the exception of up to 150 mg acetylsalicylic acids daily) within 7 days prior to receiving an injection of Xiapex is not recommended. *Immunogenicity* - As with any non-human protein medicinal product, patients may develop antibodies to the therapeutic protein. Since the enzymes in Xiapex have some sequence homology with human matrix metalloproteinases (MMPs), antidrug antibodies could theoretically interfere with human MMPs. No safety concerns related to the inhibition of endogenous MMPs have been observed, in particular no adverse events indicating the development or exacerbation of autoimmune diseases or the development of a musculoskeletal syndrome but the potential for it to occur cannot be excluded. If this syndrome were to develop, it would occur progressively and is characterised by one or more of the following signs and symptoms: arthralgia, myalgia, joint stiffness, stiffness of the shoulders, hand oedema, palmar fibrosis and thickening or nodules forming in the tendons. *Special penile conditions/diseases not studied in clinical trials* - Xiapex treatment in patients having a calcified plaque that could have interfered with the injection technique, chordee in the presence or absence of hypospadias, thrombosis of the dorsal penile artery and/or vein, infiltration by a benign or malignant mass resulting in penile curvature, infiltration by an infectious agent, such as in lymphogranuloma venereum, ventral curvature from any cause and isolated hourglass deformity of the penis has not been studied and treatment in these patients should be avoided. *Long-term safety* - Long-term safety of Xiapex is not fully characterised. The impact of treatment with Xiapex on subsequent surgery, if needed, is not known.
Drug Interactions: Use of Xiapex in patients who have received tetracycline antibiotics e.g. doxycycline, within 14 days prior to receiving an injection of Xiapex is not recommended.
Pregnancy & Lactation: Peyronie's disease occurs exclusively in adult male patients and hence there is no relevant information for use in females.
Driving and operating machinery: Minor influences on the ability to drive and use machines include dizziness, paresthesia, hypoesthesia, and headache that have also been reported following injection of Xiapex. Patients must be instructed to avoid potentially hazardous tasks such as driving or using machines until it is safe to do so or as advised by the physician.
Side Effects: Most adverse reactions were local events of the penis and groin and the majority of these events were of mild or moderate severity, and most (79%) resolved within 14 days of the injection. The adverse reaction profile was similar after each injection, regardless of the number of injections administered. The most frequently reported adverse drug reactions (> 25%) during the Xiapex clinical studies (832 male patients, 551 patients received Xiapex) were penile haematoma, penile swelling and penile pain. A popping noise or popping sensation in the penis, sometimes described as "snapping" or "cracking"and sometimes accompanied by detumescence, haematoma and/or pain, were reported in 73/551 (13.2%) Xiapex-treated patients and 1/281 (0.3%) placebo-treated patients, in Studies 1 and 2 combined. In the controlled and uncontrolled clinical studies of Xiapex in Peyronie's disease corporal rupture and other serious penile injury were reported uncommonly.
Very common (≥1/10): Penile haematoma, swelling, pain, ecchymosis.
Common (≥1/100 to <1/10): Blood blister, Skin discolouration, Penile blister, Pruritus genital, Painful erection, Erectile dysfunction, Dyspareunia, Penile erythema. Injection site vesicles, pruritus, Localised oedema, Nodule Suprapubic pain, Procedural pain.
Overdose: Overdose is expected to be associated with increased local injection site reactions. Symptomatic care and routine supportive care should be provided.
Legal Category: POM.
Marketing Authorisation Holder: Swedish Orphan Biovitrum AB (publ), SE-112 76 Stockholm, Sweden
Package Quantities, Marketing Authorisation Numbers and Basic NHS Price: XIAPEX 0.9mg powder and solvent for solution for injection, EU/1/11/671/001, £650.00.
Further information is available on request from: SOBI Ltd. 1 Fordham House Court, Fordham House Estate, Newmarket Road, Fordham, Cambs. CB7 5LL. Tel: 01638 722380
Date of Preparation: February 2015
Company Reference: SOBIUK/XIA/2015/0012

Adverse events should be reported. Reporting forms and information can be found at: www.mhra.gov.uk/yellowcard
Adverse events should also be reported to SOBI Ltd by email: drugsafety@sobi.com

XIAPEX®

collagenase clostridium histolyticum

sobi

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www.sobi-uk.co.uk

SOBIUK/XIA/2015/0017 Date of preparation: March 2015

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See www.mhra.gov.uk/yellowcard for how to report side effects.