



Medicine Supply Notification

MSN/2022/081

Nafarelin (Synarel®) 200microgram/dose nasal spray

Tier 2 – medium impact*

Date of issue: 29/09/2022

Link: [Medicines Supply Tool](#)

Summary

- Nafarelin (Synarel®) 200microgram/dose nasal spray is out of stock until late-December 2022.
- [Buserelin \(Suprecur®\) nasal 150microgram/dose spray](#) is out of stock until late-December 2022 therefore is unable to support.
- Alternative gonadotrophin-releasing hormone (GnRH) analogues (parenteral formulations) remain available. Where these are not suitable, unlicensed supplies of nafarelin nasal spray may be sourced, lead times vary.

Actions Required

Clinicians should:

- not initiate new patients on nafarelin 200microgram/dose nasal spray until the supply issue has resolved.

Where patients have insufficient supplies to last until the re-supply date, clinicians should;

- consider switching to an alternative GnRH analogue in consultation with the appropriate specialist (see supporting information below);
- where the above option is not appropriate, consider prescribing unlicensed nafarelin nasal spray. Prescribers should work with local pharmacy teams to ensure orders are placed within appropriate time frames as lead times may vary (see supporting information below); and
- if the above options are not considered appropriate, advice should be sought from specialists on management options.

When considering parenteral therapy, establish that this route of administration is acceptable to the patient, and for those switched to or initiated on a subcutaneous injection, ensure they can self-administer and are not intolerant to any of the excipients. In addition:

- Ensure the patient receives appropriate training on the administration of a subcutaneous injection and is counselled on the appropriate dose and volume to administer if self-administering.
- Signpost to online training videos if needed.
- Provide the patient with the appropriate ancillaries and a sharps bin for safe disposal of needles.

*Classification of Tiers can be found at the following link:

<https://www.england.nhs.uk/publication/a-guide-to-managing-medicines-supply-and-shortages/>

Supporting information

Clinical Information

Nafarelin (Synarel®) 200microgram/dose nasal spray contains a GnRH analogue, administered twice daily. It is licensed for the hormonal management of endometriosis, including pain relief and reduction of endometriotic lesions, and for use in controlled ovarian stimulation programmes prior to in-vitro fertilisation, under the supervision of an infertility specialist.

Off-label use

Triggering follicular maturation in in-vitro fertilisation cycles.

Self-administration of injection

In cases where it may be appropriate to train patients to self-administer the subcutaneous injection, it is recommended that initial doses should be administered under close medical supervision due to the possibility of hypersensitivity reactions. Patients should cease injections and seek medical attention should any adverse event occur, particularly an allergic reaction.

Table 1: Available parenteral GnRH analogues approved for licensed indications covered by nafarelin (Synarel®) 200microgram/dose nasal spray

Parenteral GnRH analogue	Brand and presentation	Dose	Indication
Buserelin	Suprecur® 5.5mg/5.5ml solution for injection vials*	200 – 500 microgram subcutaneous injection daily until down regulation is achieved	Pituitary desensitisation
Goserelin	Zoladex® 3.6mg implant	One 3.6 mg depot injected subcutaneously, every 28 days	Endometriosis and pituitary desensitisation
Leuprorelin	PROSTAP® SR DCS 3.75 mg powder and solvent for prolonged-release suspension for injection in pre-filled syringe	3.75 mg administered as subcutaneous or intramuscular injection every month	Endometriosis
	PROSTAP 3 DCS® 11.25 mg powder and solvent for prolonged-release suspension for injection in pre-filled syringe	One intramuscular injection every 3 months	Endometriosis
Triptorelin	Decapeptyl® SR 3mg powder and solvent for suspension for injection	One intramuscular injection every 28 days	Endometriosis
	Decapeptyl® SR 11.25mg powder and solvent for suspension for injection	One intramuscular injection every 6 months	Endometriosis

*Suprefact® injection is identical to Suprecur® injection but differs in licensed indication, although in practice, assisted conception units use these two brands of buserelin injection interchangeably, guided by stock availability. Suprefact® injection cannot support an increase in demand.

Please refer to the links below for further information:

BNF Buserelin	SmPC Suprecur®
BNF Goserelin	SmPC Zoladex®
BNF Leuprorelin	SmPC Prostav®
BNF Nafarelin	SmPC Synarel®
BNF Triptorelin	SmPC Decapeptyl®

Guidance on ordering and prescribing unlicensed imports

- The following specialist importers have confirmed they can source unlicensed nafarelin (Synarela®) 200microgram/dose nasal spray (please note there may be other companies that can also source supplies):
 - Alium Medical Limited
 - Oripfarm UK Limited
- Any decision to prescribe an unlicensed medicine must consider the relevant guidance and NHS Trust or local governance procedures. Please see the links below for further information:
 - [The supply of unlicensed medicinal products](#), Medicines and Healthcare products Regulatory Agency (MHRA)
 - [Professional Guidance for the Procurement and Supply of Specials](#), Royal Pharmaceutical Society
 - [Prescribing unlicensed medicines](#), General Medical Council (GMC),

Enquiries

Enquiries from NHS Trusts in England should in the first instance be directed to your Regional Pharmacy Procurement Specialist, who will escalate to national teams if required.

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All other organisations should send enquiries about this notice to the DHSC Medicine Supply Team quoting reference number MSN/2022/081

Email: DHSCmedicinesupplyteam@dhsc.gov.uk.