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Viagra Connect Melts, Sildenafil Citrate 50mg orodispersible film
Communication regarding new dosage form

Dear Healthcare Professional,

Summary: New orodispersible dosage form of Viagra Connect (sildenafil 50mg)

Viatris UK Healthcare Limited have obtained approval from the MHRA for the reclassification of Viagra Melts 50mg orodispersible films from a POM to P licensed medicine, which will be called Viagra Connect Melts. The aim of this communication is to inform healthcare professionals about the different formulations and mitigate any potential confusion with the new dosage form.

Viagra Connect Melts orodispersible film and Viagra Connect tablets both contain sildenafil 50mg and have the same indication of use. Pharmacists should manage this product in the same way as Viagra Connect tablets. The table below highlights the notable SmPC difference between the tablet and orodispersible film, which relates to the method of administration and excipients. Patients should be counselled on the correct use accordingly. Pharmacists may continue using the current Viagra Connect suitability checklist, which will be updated in due course to include reference to Viagra Connect Melts.

SmPC sections	**Viagra Connect TABLETS**	**Viagra Connect MELTS**
Pharmaceutical Form	Blue, diamond (shaped) film-coated tablet	Orodispersible film, pale red
Method of Administration	For oral use	For oral use The aluminum pouch should be carefully peeled open (and not cut open). The orodispersible film should be taken out with a dry finger, placed on the tongue, and allowed to disintegrate with or without water. During disintegration saliva may be swallowed, but without swallowing the film. It should be taken immediately upon removal from the pouch.
List of Excipients	Microcrystalline cellulose Calcium hydrogen phosphate (anhydrous) Croscarmellose sodium Magnesium stearate Hypromellose Titanium dioxide (E171) Lactose Triacetin Indigo carmine aluminium lake (E132)	Hydroxypropylcellulose (E463) Macrogol Crospovidone (E1202) Povidone (E1201) Sucralose (E955) Macrogol poly(vinyl alcohol) grafted copolymer Levomenthol Hypromellose (E464) Titanium dioxide (E171) Ferric oxide red (E172)

Licensed Indication

Both Viagra Connect tablets and Melts are indicated for use in adult men with erectile dysfunction, which is the inability to achieve or maintain a penile erection sufficient for satisfactory sexual performance. In order to be effective, sexual stimulation is required.

Information for Patients

During the patient consultation please advise them of the differences in method of administration and notify them that if they prefer to purchase Viagra Connect Melts that these are in place of Viagra Connect Tablets and not to be taken alongside. Please remind the patient that the maximum recommended dosing frequency is one Viagra Connect Tablet or one Viagra Connect Melts per day, if required.

Please ensure all relevant staff are made aware of the content of this letter and that the information is communicated to the relevant patients.

Viagra Connect Melts patient information

Call for reporting

Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme.

Please report:

- all suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason

You can report via:

- the Yellow Card website
- the free Yellow Card app available from the Apple App Store or Google Play Store
- some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals

Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, timing onset, treatment dates, and product brand name.

Company contact point

If you have any questions about this letter or require more information about Viagra Connect tablet or Melts please contact Viatris Medical Information at Building 4, Trident Place, Mosquito Way, Hatfield, Hertfordshire, AL10 9UL, UK. Telephone: +44 (0)1707 853 000 or email info.uk@viatris.com

Yours faithfully,

Abigail Webb
UK Medical Lead
Viatris UK