Prescription Printing Legislation Changes - Feb 2021

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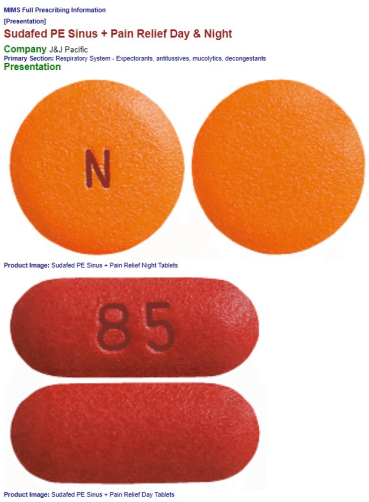
Prescribing Changes (v6.71.2 Enhancement)

A change in the National Health (Pharmaceutical Benefits) Regulations means that from 1st Feb 2021, all PBS/RPBS prescriptions will require the inclusion of active ingredient name(s)
A brand should be included only if the prescriber deems it to be clinically appropriate and when the brand name is included, the active ingredient(s) must appear first.
It is also part of wider government activity to improve consumer awareness and recognition of the active ingredients in their medicines.

The Full MIMS Full Prescribing Information is now updated,

Example: The old version of MIMF Full Prescribing Information was ;



Its been now updated to a more detailed view ;

Jetrea

MIMS Full Prescribing Information
Company I-Care Pharma Distributors Pty Ltd
MIMS Class Eye - Other ophthalmic medication
MIMS revision date 01 Oct 2019

1 Name of the Medicine

Jetrea solution for injection. Ocriplasmin (ryp).

2 Qualitative and Quantitative Composition

Ocriplasmin (ryp) is a recombinant truncated form of human plasmin with a molecular weight of 27.2 kDa produced by recombinant DNA technology in a *Pichia pastoris* expression system.
Each vial contains 0.5 mg ocriplasmin and 0.21 mg citric acid, 0.75 mg mannitol, sodium hydroxide (for pH adjustment) and water for injections with a pH of 3.1.
Jetrea drug product solution is to be diluted with an equal volume of 0.9% (w/v) sodium chloride prior to use. After dilution with 0.2 mL of 0.9% sodium chloride (preservative-free), 0.1 mL

3 Pharmaceutical Form

Jetrea is concentrated solution for intravitreal injection (a sterile, clear and colourless solution).

4 Clinical Particulars

4.1 Therapeutic Indications

Jetrea is indicated in adults for the treatment of vitreomacular traction (VMT), including when associated with macular hole of diameter less than or equal to 400 microns.

4.2 Dose and Method of Administration

Dosage. The diagnosis of vitreomacular traction (VMT) should comprise of a complete clinical picture, including patient history, clinical examination and investigation using currently accept
Jetrea solution for injection must be prepared and administered by a qualified ophthalmologist experienced in intravitreal injections. Single use vial is for intravitreal use only.
The recommended dose is 0.125 mg (0.1 mL of the diluted solution) administered by intravitreal injection to the affected eye once as a single dose.
Each vial should only be used once and for the treatment of a single eye. Administration to both eyes concurrently or within 7 days of the initial injection is not recommended in order to mo
administration in the same eye is not recommended.
Dosage adjustment in. *Renal impairment.* No formal studies have been conducted with ocriplasmin in patients with renal impairment. No dose adjustment or special considerations ar
Hepatic impairment. No formal studies have been conducted with ocriplasmin in patients with hepatic impairment. No dose adjustment or special considerations are anticipated for patie
Preparation for administration. To prepare Jetrea for intravitreal injection, adhere to the following instructions.
1. Remove the vial from the freezer and allow to thaw at room temperature (takes about 2 minutes).
2. Once completely thawed, remove the protective polypropylene flip off cap from the vial.
3. Disinfect the top of the vial with an alcohol wipe.
4. Using aseptic technique, dilute by adding 0.2 mL of sodium chloride 9 mg/mL (0.9%) solution for injection (sterile, preservative-free, non-buffered) into the Jetrea solution for injection v
The diluent should be withdrawn from an unopened container which should be used only once. The remaining sodium chloride 9 mg/mL (0.9%) solution for injection should be discarded. Th
5. Visually inspect the vial for particulate matter. Only a clear, colourless solution without visible particles should be used.
6. Using aseptic technique, withdraw all of the diluted solution using an appropriate sterile needle (slightly incline the vial to ease withdrawal) and discard the needle after withdrawal of the
7. Replace the needle with an appropriate sterile needle, carefully expel the air from the syringe and adjust the dose to the 0.1 mL mark on the syringe (corresponding to 0.125 mg ocriplas
8. Inject 0.1 mL of the diluted solution without delay into the midvitreous as it contains no preservatives.
9. Discard the vial and any unused portion of the diluted solution after single use.
Following 1:1 dilution with 0.9% w/v Sodium Chloride Injection, USP (sterile, preservative free), 0.1 mL of the diluted solution should be used for intravitreal injection. Vial is for single use
Administration. The intravitreal injection procedure should be carried out under controlled aseptic conditions, which include the use of surgical hand disinfection, sterile gloves, a sterile d
The periocular skin, eyelid and ocular surface should be disinfected and adequate anaesthesia and a broad-spectrum topical microbiocide should be administered according to standard medi
The injection needle should be inserted 3.5-4.0 mm posterior to the limbus aiming towards the centre of the vitreous cavity, avoiding the horizontal meridian. The injection volume of 0.1 m

4.3 Contraindications

Patients with active or suspected ocular or periocular infections.
Patients with known hypersensitivity to ocriplasmin or to any of the excipients of Jetrea.

4.4 Special Warnings and Precautions for Use

Decreased vision. A decrease of greater than or equal to 3 lines of best corrected visual acuity (BCVA) was experienced by 5.6% of patients treated with Jetrea and 3.2% of patients trea
due to progression of vitreomacular traction and many patients required vitrectomy (see Section 5.1 Pharmacodynamic Properties, Clinical trials).

This change will also reflect in the way the drugs are getting printed.

As per the new legislation, the prescription should include the brand name and the active ingredient.

Eg: Drug: **Lamictal 50mg**

Brand name: **Lamictal Chewable tablets**

Active ingredient : **Lamotrigine**

2021-01-20 Script ID: 149

X X

Lamotrigine 50mg Chewable Tablet 50 mg [56], (Lamictal)
test
Quantity: 56. 5 repeats.

1 item(s) printed

2021-01-20 Script ID: 149

X X

Lamotrigine 50mg Chewable Tablet 50 mg [56], (Lamictal)
test
Quantity: 56. 5 repeats.

1 item(s) printed

Another change is the inclusion of a new field '**Include Brand Name on Script**' - A new checkbox is added when prescribing a drug allow doctors to include brand name on the script.

This checkbox will be checked by default if the user has selected **brand substitution not permitted** as the brand is necessary to dispense script.

Dosage - Crestor Tablets (Tablets) 40 mg [30]

- [x] Pbs
- [x] Rpbs
- [ ] Brand Substitution Not Permitted
- [ ] Include Brand Name On Script
- [ ] Authority
- [ ] Previous Authority

Dosage	Frequency	Instruction
	Select from list	Select from list