**Early Access Program**

***Irminix*®**

Warning: Do not acquire and use a counterfeit, Chinese made product. More info on www.emeramed.com

**(INN: *Emeramide* – Code: *NBMI*)**

***Dear Patient or Physician: Before emailing questions, please first fill in and send us the basic patient information below. And please read and follow the steps described on the next page.***

Drugs under development may be approved for use by a regulatory authority on an *Individual Patient Use* basis. This is also called Expanded Access, Named Patient Use, or Compassionate Use, depending on the country. The approval is based on whether the condition to be treated is serious enough, whether efficient and safe treatments are existing or lacking, and whether the drug has shown relevant efficacy and safety. **Only a licensed physician can be responsible for prescribing the treatment.**

Currently, we can offer a 14-day treatment x 300mg per day. The treatment length and dosing are determined by the length of the Phase 1 and 2a clinical studies that have been performed. Treatment quantities depend on the individual patient – some require several treatments, typically with 28 days in between. There is no charge for the drug, but a cost of €600 for insurance-Shipping-Administration per two-week-treatment.

MedSafe permits the use of unapproved medicines under Section 25 of the Medicines Act (see <http://www.medsafe.govt.nz/profs/riss/unapp.asp>).

The terms of section 25 are inclusive and permissive, allowing the authorised prescriber to "procure the sale or supply of any medicine" for a particular patient in his or her care. "Any medicine" includes approved and unapproved medicines. The authorised prescriber must always be working within his / her scope of practice when exercising this right.

"Procure the sale or supply" refers to obtaining the medicine through the usual channels such as a pharmacy or a pharmaceutical company, and it also permits the authorised prescriber to use other means of obtaining a medicine such as importation. However, section 25 does not envisage bulk purchase by the authorised prescriber. The use is to be for the treatment of a particular patient in the care of that or another authorised prescriber.

**How to obtain *Irminix*®**

1. Complete the form on the next page
2. The physician signs the form to confirm that information supplied is correct and that, as an authorised prescriber, he or she understands his or her responsibilities under Section 25 of the Medicines Act
3. The physician sends the following documents in one email to earlyaccess@emeramed.com:
	1. Prescription (this is the signed form on the next page)
	2. Physician’s license as a PDF, in date and showing a verifiable registration number
	3. Informed consent form signed by physician and patient
4. The drug is dispatched to the physician. There is no charge for the drug but a cost of €600 is invoiced for insurance, shipping and administration per treatment
5. 1 to 3 months after treatment, an After-Treatment-Report form is filled in and sent to earlyaccess@emeramed.com. The patient may send this in, unless that there have been adverse events which the physician reports.

**Prescription**

|  |  |
| --- | --- |
| \*Date of Request (DD/MMM/YYYY): | Click here to enter a date. |
| **Patient**  |
| \*Name: | <enter first and last name> |
| **\*** Address: |       |
| **\*** Zip code & City |       |
| **\*** Country: |       |
| \*E-mail: |       |
| \*Age: |       |
| \***Briefly describe the disease/indication intended to be treated.** **Patient medical history/current physical condition, summary of any relevant tests done with dates & rationale for request to use Irminix:**        |
| \* **Briefly describe previous use of metal chelators (such as DMPS, DMSA, BAL, EDTA and OSR#1). When were they used? How much was taken per day and how long? What were the results on health and on metal tests and other tests?**        |
| \* **Briefly describe current treatments, medications, including herbals and other dietary supplements.**        |

|  |
| --- |
| **Physician**  |
| \*Name: |       |
| **\*** Address: |       |
| **\*** Zip code |       |
| **\*** Country: |       |
| \*E-mail: |       |
| \*Tel: |       |
| *Shipping address if other than the above – we can only ship to physician or clinic not to patient* |
| *Address for shipping:* |       |
| *Zip code & City* |       |
| *Country:* |       |
| *Number of treatments prescribed*  |
| *Number of treatments (each 14 days x 3 capsules of 100mg)* |       |

**I am an authorised prescriber registered with MedSafe and I understand my responsibilities when importing Irminix into New Zealand under Section 25 of the New Zealand Medicines Act 1981.**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

***Physician’s signature***