**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:
- US-Citizens: Do not use this document but follow link at https://emeramed.com/early-access/***

***- Non-US Citizens: Read and follow the steps described on the next page***

Drugs under development can 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. The physician is responsible for the treatment. In most countries, **only a licensed physician can apply to the regulatory authority.** To date, we have experience with approvals and shipping to Switzerland, Germany, Austria, New Zealand, Lebanon and the USA. Most US patients and physicians finds the FDA process too complicated and instead go to Germany or NZ.

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. If this is enough depends 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 (appr. $680) for insurance-Shipping-Administration per two-week-treatment.

*No approval by the regulatory authority needed for the physician to order the drug:*

* **New Zealand:** Section 25 of the Medicines Act permits the physician to import drugs for individual patients<http://www.medsafe.govt.nz/profs/riss/unapp.asp>
* **Lebanon:** Ministry of Public Health approved the import of Irminix for individual patient use.
* **Switzerland:** Article 49 of the 2018 Regulation for the Authorisation of Medicines permit an attending physician holding a cantonal licence to import small quantities of human medicine for Compassionate Use for the treatment of a given patient. (<https://www.admin.ch/opc/de/classified-compilation/20180857/index.html>)

*Approval by the regulatory authority not required under certain circumstances:*

* **Austria:** Named Patient Use <http://www.basg.gv.at/fileadmin/user_upload/L_I236_Information_Named_Patient_Use_en.pdf>
* **Germany:** The physician contacts the regulatory authority in the region.

*Approval from regulatory authority required in most countries***:**

* **Switzerland:** *Sonderbewilligung*. We provide the application filled in.
* **Sweden:** *License* <https://lakemedelsverket.se/licens>
* **Denmark:** *Compassionate Use to named patient*<https://sundhedsstyrelsen.dk/en/medicines/regulation/compassionate-use-permits>
* **UK***: Individual Patient use, Specials.* A company needs to import the drug for the physician; this will be explained to the physician by contacting earlyaccess@emeramed.com. [www.gov.uk/government/uploads/system/uploads/attachment\_data/file/373505/The\_supply\_of\_unlicensed\_medicinal\_products\_\_specials\_.pdf](http://www.gov.uk/government/uploads/system/uploads/attachment_data/file/373505/The_supply_of_unlicensed_medicinal_products__specials_.pdf)
* **Australia:** *Special Access Scheme* <https://www.tga.gov.au/form/special-access-scheme>
* **Canada:** *Special Access Program* <http://www.hc-sc.gc.ca/dhp-mps/acces/drugs-drogues/index-eng.php>
* **US:** *Individual Patient IND under Expanded Access for Non-emergency or Emergency Use*. Note that this is a complicated process. Read more at [www.emeramed.com/earlyaccess](http://www.emeramed.com/earlyaccess)
* **And most other countries**

**How to obtain *Irminix*® & Prescription**

**1a. Email the below info to *earlyaccess@EmeraMed.com.* Filled in by Patient or Physician.**

|  |  |
| --- | --- |
| \*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.**        |

**1b. Prescription *(If there is yet no physician, leave blank. It will need to be signed later on.)***

|  |
| --- |
| **Physician**  |
| \*Name: |       |
| **\*** Address: |       |
| **\*** Zip code |       |
| **\*** Country: |       |
| \*E-mail: |       |
| \*Tel: |       |
| *Shipping address if other than the above – we can only ship to physician, clinic or pharmacy, 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)* |       |

**Note 1, for New Zealand Physicians:** The signature means that this statement applies: *“I am an authorised prescriber registered with MedSafe and I understand my responsibilities when importing Irminix into New Zealand under Section 25 of the Medicines Act.”*)

**Note 2, for Swiss physicians:** The signature means that the physician holds a cantonal authorisation to practice medicine and that this statement applies: *“I understand my responsibilities when importing Irminix into Switzerland under Article 49 of the 2018 Verordnung über die Bewilligungen im Arzneimittelbereich/Ordonnance sur les authorisations dans le domaine des medicaments and in particular paragraphs 2 a and b.”*

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***Physician’s signature***

**2. If accepted by the Company, the physician will be provided with documents to send to the regulatory authority.**

**3. Physician applies to the regulatory authority (if required, see previous page; not required in NZ or Lebanon).**

**4. Physician sends the following documents *in one email* to EarlyAccess@EmeraMed.com:**

1. *Prescription* (this is this document, with signature above)
2. *Approval* from the regulatory authority (if required; see previous page) *in English* (or the original + a translation to English)
3. *Physician’s license*, copy as PDF
4. *Informed consent* form signed by physician and patient

 **5. An invoice is emailed to the physician with the fee of €600 (appr. $680) for insurance-Shipping-Administration. It can be paid with credit card.**

**6. The drug is dispatched to the physician.**

**7. 1-3 months after treatment, the patient or the physician fills in the After-treatment-report form found in the Informed Consent and send to EarlyAccess@EmeraMed.com.**