EmeraMed Limited
Trinity House
Charleston Road, Ranelagh
Dublin 6, Ireland

Early Access Program
Irminix®

(INN: *Emeramide* – Code: *NBMI*)

The use of drugs under development can be approved by a regulatory authority on a *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. In general **only a licensed physician can apply to the regulatory authority.** The physician is responsible for the treatment. To date, we have experience with approvals and shippings to Switzerland, Germany, Austria, New Zealand, Lebanon and the USA.

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

- **New Zealand:** Section 25 of the Medicines Act permits use of unapproved medicines http://www.medsafe.govt.nz/profs/riss/unapp.asp
- **Lebanon:** Ministry of Public Health has approved the import of Irminix for individual use.

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 BFARM who responds by email that the physician may use the drug at his/her responsibility; that email, we need.

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 a physician; this has been arranged for one physician. 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 that demands some five documents to be submitted and that not only FDA approval is required, but that also an Institutional Review Board (IRB) is required to oversee the actual treatment. http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/ucm107434.htm
- **And most other countries**

Treatment with *Irminix*®

Currently, we are allowed to offer a 14-day treatment x 300mg per day. The treatment length and dosing are limited by the length of the Phase 1 and Phase 2a clinical studies that have been performed. If this is enough for the individual patient or not, we cannot answer. In clinical trials on mercury intoxicated gold miners, in half of the there have been major positive effects while in half no noticeable effects (all of the latter have had high to extreme mercury levels, so, possibly the latter needed higher doses and/or longer treatment).

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How to obtain *Irminix*®

1. Physician fills in this prescription and emails to *earlyaccess@EmeraMed.com*

Prescription/Request for 14 day treatment of 300 mg Irminix®

*Date of Request (DD/MMM/YYYY):	Click here to enter a date.
Physician	
*Name:	<enter first and last name>
* Address:	<insert country>
* Zip code	<insert country>
* Country:	<insert country>
*E-mail:	
*Tel:	
Shipping address if other than the above	
* *Address for shipping:*	*<insert country>*
* *Zip code*	*<insert country>*
* *Country:*	*<insert country>*
Patient	
*Name:	<enter first and last name>
* Country:	<insert 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 patient's current treatments, medications, including herbals and other dietary supplements.**	

2. If accepted by the Company, the physician will be provided with a document that is to accompany his/her application to the regulatory authority, and an Informed Consent form.

3. Physician applies to the regulatory authority.

4. Physician sends to EarlyAccess@EmeraMed.com:

A. *Approval* from the regulatory authority (if required; see previous page) *in English* (or the original + a translation to English)
B. *Physician's license*, copy as PDF
C. *Informed consent* form signed by physician and patient

Please send all these documents in one email to avoid administrative delays.

5. The drug is dispatched within 1-2 days. An invoice is emailed to the physician – there is no charge for the drug, but a cost of €600 ($750) for insurance-Shipping-Administration.

6. 1-3 months after treatment, please fill in the After-treatment-report form on the next page and send to EarlyAccess@EmeraMed.com. The patient may send this in, unless that there have been adverse events which the physician reports.