Checklist for the prescription of Eurartesim (dihydroartemisinin/ piperaquine tetraphosphate) in your patients

REVISED EDITION 2016

The following checklist provides a brief reference guide to conditions and medications that are contraindicted for the use of Eurartesim. The checklist is designed to assist you in determining your patient's suitability for treatment with Eurartesim and should be completed in the presence of the patient or their carer. If checklist items 1–9 are all answered "No" the patient is potentially eligible for prescription with Eurartesim. Additional information regarding Eurartesim can be found in the accompanying educational guide for healthcare professionals.

Please complete both sides of the checklist, ticking the appropriate answer.

	Contraindicated conditions for use	**Yes**	**No**
1.	**Is the patient hypersensitive to any of the active substances or excipients?**	☐	☐
2.	**Does the patient have severe malaria (WHO definition)?**	☐	☐
3.	**Does the patient have a family history of sudden death or of congenital prolongation of the QTc interval?**	☐	☐
4.	**Has the patient suffered from congenital prolongation of the QTc interval or any clinical condition known to prolong the QTc interval?**	☐	☐
5.	**Does the patient have a history of symptomatic cardiac arrhythmias or clinically relevant bradycardia?**	☐	☐
6.	**Does the patient have predisposing cardiac conditions for arrhythmia such as severe hypertension, left ventricular hypertrophy (including hypertrophic cardiomyopathy) or congestive cardiac failure accompanied by reduced left ventricle ejection fraction?**	☐	☐
7.	**Does the patient have known electrolyte disturbances, particularly hypokalaemia, hypocalcaemia or hypomagnesaemia?**	☐	☐

Contraindicated concomitant medications	Yes	No
8. **Is the patient currently receiving medications that are known to prolong the QTc interval? These include (but are not limited to):** • **Antiarrhythmics (e.g. amiodarone, disopyramide, dofetilide, ibutilide, procainamide, quinidine, hydroquinidine, sotalol)** • **Neuroleptics (e.g. phenothiazines, sertindole, sultopride, chlorpromazine, haloperidol, mesoridazine, pimozide, thioridazine) and antidepressive agents** • **Certain antimicrobial agents, including some agents of the following classes:** o **Macrolides (e.g. erythromycin, clarithromycin)** o **Fluoroquinolones (e.g. moxifloxacin, sparfloxacin)** o **Imidazole and triazole antifungal agents** o **Pentamidine and saquinavir** • **Certain non-sedating antihistamines (e.g. terfenadine, astemizole, mizolastine)** • **Cisapride, droperidol, domperidone, levomethadyl, methadone, arsenic trioxide, vinca alkaloids, bepridil, diphemanil or probucol**	☐	☐
9 **Has the patient recently been treated with antimalarial medications that are known to prolong the QTc interval, and may still be present in their circulatory system, including chloroquine, halofantrine, lumefrantrine, mefloquine and quinine? Does the patient have severe malaria (WHO definition)?**	☐	☐

If checklist items 1–9 are all answered “No” the patient is potentially eligible for prescription with Eurartesim. In addition, make sure to respect the administration conditions described in the SmPC (Eurartesim should be administered with water three hours apart from food intake), as food might increase piperaquine absorption causing increased plasma levels and, therefore, QTc interval prolongation.

For full prescribing information please refer to the Summary of Product Characteristics.

Close ECG monitoring should be considered for patients who are receiving medications that may interfere with Eurartesim metabolism, including protease inhibitors (e.g. amprenavir, atazanavir, indinavir, nelfinavir, ritonavir), nefazodone or verapamil.

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions.

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via: HPRA Pharmacovigilance, Earlsfort Terrace, IRL-Dublin 2; Tel: +3531 6764971; Fax: +3531 6762517. Website: www.hpra.ie; Adverse events should also be reported to Sigma-Tau Industrie Farmaceutiche Riunite S.p.A,

email: Pharmacovigilance@sigma-tau.it,

Fax: +39 06 9139 4007

Phone: +39 06 9139 3360.