7 May 2018[1]
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Pharmacovigilance Risk Assessment Committee (PRAC)

Nýr texti fyrir lyfjaupplýsingar – Útdráttur úr ráðleggingum PRAC vegna ræsimerkja

Samþykkt á fundi PRAC 9.-12. apríl 2018

Textinn í þessu skjali fyrir lyfjaupplýsingar er útdráttur úr skjali sem nefnist 'PRAC ráðleggingar vegna ræsimerkja (*PRAC recommendations on signals*)' en í því skjali er heildartexti með ráðleggingum PRAC um uppfærslu á lyfjaupplýsingum ásamt almennum leiðbeiningum um hvernig skuli afgreiða ræsimerki. Skjalið er hægt að nálgast ***hér*** (aðeins á ensku).

Nýr texti sem bæta á við lyfjaupplýsingar er undirstrikaður. Texti sem á að eyða er ~~yfirstrikaður.~~

1. Amitriptylin – Augnþurrkur (EPITT nr. 19173)

Samantekt á eiginleikum lyfs

4.8. Aukaverkanir

Undir líffæraflokknum "Augu"

Tíðni ekki þekkt: Augnþurrkur.

Fylgiseðill

4. Hugsanlegar aukaverkanir

Tíðni ekki þekkt: Augnþurrkur.

2. Dasatinib – Cýtómegalóveira (CMV) endurvirkjun (EPITT nr. 19111)

Samantekt á eiginleikum lyfs

4.8. Aukaverkanir

[1] Intended publication date. The actual publication date can be checked on the webpage dedicated to PRAC recommendations on safety signals.

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Tafla 2: Samantekt yfir aukaverkanir í töflu.

Sýkingar af völdum sýkla og sníkjudýra
Algengar: lungnabólga (þ.m.t. af völdum baktería (sýkla), veira og sveppa), sýking/bólga í efri öndunarvegi, herpes veirusýking (þ.m.t. cýtómegalóveira – CMV), sýking vegna garnar- og ristilbólgu, sýklasótt (þ.m.t. sjaldgæf tilfelli sem geta verið banvæn)

Fylgiseðill

4. Hugsanlegar aukaverkanir

Algengar aukaverkanir (geta komið fyrir hjá allt að einum af hverjum 10 einstaklingum)

Sýkingar: lungnabólga, veirusýking af völdum herpes (þ.m.t. cýtómegalóveira – CMV), sýking í efri öndunarvegi, alvarleg sýking í blóði og vefjum (þar með talið sjaldgæf tilfelli sem geta verið banvæn)

3. Lapatinib – Lungnaháþrýstingur (EPITT nr. 19089)

Samantekt á eiginleikum lyfs:

4.8 Aukaverkanir

Tíðni ekki þekkt: lungnaslagæðaháþrýstingur

Fylgiseðill

4. Hugsanlegar aukaverkanir

Tíðni ekki þekkt: lungnaslagæðaháþrýstingur (hækkaður blóðþrýstingur í lungnaslagæðum)

4. Phenprocoumon – Risk of birth defects and foetal loss following first trimester exposure as a function of the time of withdrawal (EPITT no 18902)

No product with an Icelandic marketing authorisation falls within the scope of this PRAC recommendation. Therefore the text has not been translated into Icelandic /Ekkert lyf með íslenskt markaðsleyfi fellur undir þessa ákvörðun PRAC. Textarnir hafa því ekki verið þýddir á íslensku.

Summary of product characteristics

4.6. Fertility, pregnancy and lactation

Women of childbearing potential / Contraception

Women of childbearing age who are taking <…> have to use effective contraceptive measures during treatment and should continue for 3 months after the last dose.

Women of childbearing potential planning a pregnancy should be switched to a safer alternative treatment prior to pregnancy.

Pregnancy

Based on human experience phenprocoumon may cause birth defects and foetal death when administered during pregnancy. There is epidemiological evidence suggesting that the risk of birth defects and foetal death increases with the increasing duration of exposure to phenprocoumon during the first trimester of pregnancy, with a steep increase of the rate of major birth defects when phenprocoumon treatment is continued beyond the 5th gestational week.

In cases of exposure to phenprocoumon during second and third trimester of pregnancy, the foetus is at an increased risk of intrauterine or parturitional (cerebral) hemorrhage due to foetal anticoagulation.

In humans phenprocoumon crosses the placental barrier.

Phenprocoumon is contraindicated during pregnancy (see section 4.3).

If the patient becomes pregnant while taking <…>, the patient should immediately be switched to a safer alternative treatment (e.g. heparin) and close follow-up including level II ultrasound should be recommended.

Breastfeeding

In nursing mothers, the active ingredient passes into the breast milk, though in such small amounts that no adverse reactions are likely to occur in the infant. As a precaution, however, prophylaxis involving the administration of vitamin K1 to the infant concerned is recommended.

Fertility

No information on effects of <…> on fertility is available.

Package leaflet

2. What you need to know before you take <…>

Pregnancy, breastfeeding and fertility

Pregnancy

You must not use <…> when you are pregnant, as it passes from mother to child. This means taking <...> during pregnancy can lead to malformations and even death of your unborn child. There is also a risk of bleeding in the foetus (foetal hemorrhage).

You must prevent becoming pregnant by taking effective contraceptive measures during therapy with <…> and in the period of 3 months after completion of the treatment with <…> due to the increased risk of foetal malformations.

If you wish to get pregnant or if you already became pregnant while taking this medicine, talk to your doctor immediately as you should be switched to a safer alternative treatment (e.g. heparin) if you are planning a pregnancy or immediately after recognition of pregnancy.

Breastfeeding

If you are breastfeeding, <…> passes into the breast milk, though in such small amounts that no adverse reactions are likely to occur to your child. Therefore, if you are breastfeeding, your child should receive vitamin K1.

Fertility

No information is available regarding the influence of <…> on fertility.

5. Vortioxetin – Ofsabjúgur og ofsakláði (EPITT nr. 19099)

Samantekt á eiginleikum lyfs

4.8. Aukaverkanir

Tafla yfir aukaverkanir

Húð og undirhúð

Tíðni ekki þekkt: Ofsabjúgur, ofsakláði.

Fylgiseðill

4. Hugsanlegar aukaverkanir

Tíðni ekki þekkt (ekki hægt að áætla út frá fyrirliggjandi gögnum)

- Þroti í andliti, á vörum, tungu eða í hálsi.
- Ofsakláði