Te Awakairangi Health NETWORK

September 2016

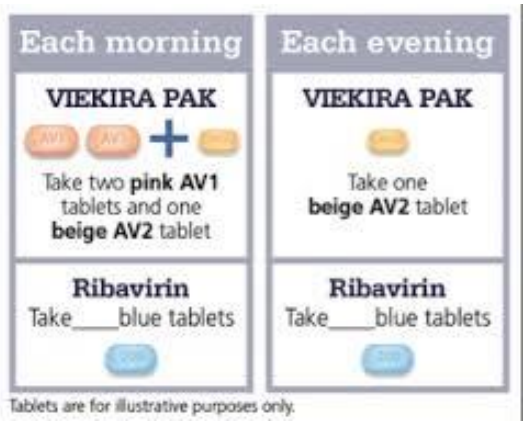
Viekira Pak – a cure for hepatitis C patients?

Background

In New Zealand, there are approximately 20,000 people who have been diagnosed with chronic hepatitis C, with a further 30,000 thought to have chronic hepatitis C but who aren't yet diagnosed with the disease. Current data also suggests that Māori are over represented in the population living with chronic hepatitis C.
Six different hepatitis C genotypes have been identified with the New Zealand prevalence for genotype 1 thought to be 57%. The Hutt Valley has approximately 370 patients who have a current diagnosis of hepatitis C genotype 1.

There are two medicine combinations indicated for the treatment of hepatitis C genotype 1:

- paritaprevir with ritonavir and ombitasvir with dasabuvir, also known under the brand name **Viekira Pak**, and
- paritaprevir with ritonavir and ombitasvir with dasabuvir plus ribavirin, with the brand name **Viekira Pak-RBV**.



Mechanism of Action, Trial results

VIEKIRA PAK combines three direct-acting hepatitis C virus (HCV) antiviral agents with distinct mechanisms of action and non-overlapping resistance profiles to target the virus at multiple steps in the viral lifecycle. Ritonavir is a pharmacokinetic enhancer that increases peak and trough plasma drug concentrations of paritaprevir and overall drug exposure.

Sustained virologic response (SVR; virologic cure) was defined as unquantifiable or undetectable HCV RNA 12 weeks after the end of treatment (SVR12) in the Phase 3 trials.

	Genotype 1a		Genotype 1b	
	No cirrhosis VIEKIRA PAK-RBV	With cirrhosis VIEKIRA PAK-RBV	No cirrhosis VIEKIRA PAK	With cirrhosis VIEKIRA PAK-RBV
	12 weeks	12 weeks*	12 weeks	12 weeks
Treatment naïve	96% (403/420)	92% (61/66)	100% (210/210)	100% (22/22)
Treatment experienced	96% (166/173)	94% (64/68)	100% (91/91)	98% (45/46)
TOTAL	**96% (569/593)**	**93% (125/134)***	**100% (301/301)**	**99% (67/68)**

*All subjects received 12 weeks of therapy except for genotype 1a infected prior null responders with cirrhosis who received 24 weeks of therapy.

More than 90% of people who take Viekira Pak or Viekira Pak-RBV for their chronic hepatitis C will be free of the virus 12 weeks after their treatment has stopped.

Prescribing Viekira Pak or Viekira Pak-RBV

All patients with cirrhosis should be managed in secondary care because of increased risks of serious adverse events during Viekira Pak therapy. Patients also need long-term hepatocellular carcinoma surveillance after treatment.

Patient Population	Treatment	Duration	RBV Daily Dose
GT1b without cirrhosis	VIEKIRA PAK	12 weeks	N/A
GT1a without cirrhosis	VIEKIRA PAK-RBV†	12 weeks	<75kg = 1000 mg ≥75kg = 1200 mg RBV is to be taken in two divided doses, morning and evening.
GT1 with cirrhosis (except GT1a prior null responders)^	VIEKIRA PAK-RBV	12 weeks	
GT1a cirrhotic prior null responders^	VIEKIRA PAK-RBV	24 weeks	

Interactions

Metabolism of Viekira Pak involves enzymes CYP3A and CYP2C8. Strong CYP2C8 inhibitors and inducers and moderate or strong CYP3A inducers should not be co-administered with Viekira Pak.

- Fluticasone, salmeterol, ethinyl estradiol, atorvastatin, simvastatin, quetiapine, midazolam, triazolam, carbamazepine, phenytoin, should be avoided (not a complete list).
- Ethinyl estradiol containing medications eg combined oral contraceptives must be discontinued at least 2 weeks prior to starting Viekira Pak treatment due to potential for ALT elevations. Two alternative methods of contraception is essential for both men and women as pregnancy should be avoided for all patients and their partners.
- Fluticasone exposure can be greatly increased with cases of Cushing's syndrome occurring. Beclomethasone is a safe alternative.
- Quetiapine dose needs to be reduced to a sixth of current dose.

What can you do?

1. Identify patients with Hepatitis C genotype 1.
2. Liver elastography scan and bloods should have been completed by Hepatitis Foundation. If scan shows cirrhosis then refer to secondary care for treatment.
3. Drug interaction check. (can call pharmacist at Teahn)
4. Prescribe Viekira Pak or Viekira Pak-RBV and complete Distribution request form (PHARMAC).
5. Ongoing monitoring for 12 weeks of treatment and 12 weeks post treatment.
6. Provide targeted testing of individuals at risk of hepatitis C exposure.

Resources

http://hep-druginteractions.org/checker
www.viekira.co.nz
https://www.pharmac.govt.nz/assets/viekira-pak-form.docx
http://www.nzsg.org.nz/cms2/news/13/15/Hepatitus-C/