Real Harvoni and Generic Harvoni

July 22, 2016 By Greg Jefferys

I had an email today asking about the differences between Generic Harvoni and the “real” Harvoni and thought that I should share my answer in my blog:

Firstly you should understand that there is ’real’ Harvoni that costs around $80,000 and then three types of generic Harvoni. Harvoni is a combination of Sofosbuvir 400 mg and Ledipasvir 90 mg in one tablet. There are probably some ingredients included in the tablet that assist with absorption of the Ledipasvir, which is slightly insoluble.

1. The licensed generic Harvoni.
This is made in India by four licensed manufacturers who pay Gilead a royalty for everything they sell. The four licensed manufacturers are Hetero Pharmaceuticals, Natco, Cipla and Mylan. However of these four only two actually manufacture the active ingredients. These two are Hetero and Natco. The other two buy the APIs (Active Pharmaceutical Ingredients) from Hetero and Natco and just make them into tablets.
However these four licensed manufacturers all pay a royalty to Gilead and in exchange for that royalty Gilead has provided them with all the intellectual property to make Harvoni.
In the case of the licensed generic Harvoni the product is IDENTICAL to the ’real’ Harvoni because part of the license agreement and the reason the royalty is paid, is that Gilead gave these four companies all the intellectual property and manufacturing technology. So the licensed generics are identical to Harvoni.

2. Unlicensed generics.
There are several sources of unlicensed generic Harvoni, these include to companies in Bangladesh. Incepta is the most well known and makes Twinvir. Another Bangladeshi company called Beacon makes both generic Harvoni and also Darvoni. Darvoni is a combination of Sofosbuvir and Daclatasvir in one tablet and is not a generic Harvoni. They both make unlicensed versions of Harvoni using APIs imported from China. Whilst the chemical content of the active ingredient (sofosbuvir 400 mg and ledipasvir 90 mg) is the same we do not know that technology to improve the absorption of Ledipasvir is the same as in Harvoni (Ledipasvir is not very soluble)
Another source of unlicensed generic Harvoni is from Australia. Several Australian pharmacies use imported Chinese APIs purchased from an Australian government approved importer. These pharmacies are all well qualified and licensed and they provide the generic version of Harvoni in two separate capsules, one containing 400 mg of Sofosbuvir and the other containing 90 mg of Ledipasvir. These capsules are take at the same time.

Whilst recent tests results indicate that there is no significant difference in the cure rates between licensed generic Harvoni and unlicensed generic Harvoni I generally recommend that people use the licensed generics rather than the unlicensed generics. For even though the evidence indicates that cure

rates are the same across the board... even if there is only one or two percent difference in the results it is important.
Of course there are other factors. The cost of unlicensed generic Harvoni is always going to be a little cheaper because no royalties are being paid. Perhaps the cost will by a couple of hundred dollars per treatment cheaper and this will be important for a lot of people.

Current Prices of Generic Hep C Medicines in India

When generic Harvoni was released in India in December 2015 the cost was around US$2,000 for a 12 week treatment however as production and competition increased the price has gradually dropped.
This week, in mid-July 2016 the cost of generic Harvoni in India dropped again and now generic Harvoni can be purchased in India for around US$1,000 or a little less. As with all products different brands and different suppliers have different prices but if you actually go to India yourself and purchase generic Harvoni, of any brand, you will not pay more than US$1,000 for a 12 week treatment of 84 tablets.
You may get it a fair bit cheaper too if you shop around however I would warn against buying “bargain” priced generic Harvoni. The two components of Harvoni, Sofosbuvir and Ledipasvir are “commodities” and they have a specific cost of manufacture and therefore a specific value, like petrol or computers. So if something is very cheap, if someone offers you a 12 weeks treatment of generic Harvoni for say US$450 then I would suggest extreme caution and suspicion. If it is too cheap there will be a reason. Maybe fake, maybe past its expiry date.
It is not something that you want to buy from a suspect source. If you have gone to all the trouble of traveling to India buy from a reliable supplier not a back alley dude.
There is no point in saving a couple of hundred dollars and discovering that your meds have past their expiry date or something worse. Pay the right price and get the right meds.

Now what I have just written applies to generic Harvoni. The cost of a 12 week treatment of generic Sofosbuvir is basically the same as a treatment of generic Harvoni.
If you travel to India and buy from a reliable supplier then you should expect to pay around US$1,000 for a 12 weeks supply of licensed generic Sofosbuvir and Daclatasvir. These will come in separate tablets so you will get 84 tablets of Sofosbuvir and 84 tablets of Daclatasvir.

Lastly please remember that these prices are if you go to India and purchase in India and carry your medicines home with you. If you want to have generic Harvoni or Sofosbuvir + Daclatasvir sent to you by mail or by courier then you will obviously have to pay more.
The most you should pay to have a 12 week treatment of generic Harvoni sent to you by door to door courier is US$1,200. The same will apply to Sofosbuvir and Daclatasvir.

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