

DNA, Mumbai

Friday 13th December 2013, Page: 11

Width: 20.62 cms, Height: 11.53 cms, 4r, Ref: pm1n.2013-12-14.13.27

FOR PEACE OF MIND! Five firms get FDA nod to sell cheaper generic versions of antidepressant Cymbalta in US market

Now, Indian companies to shoo away US blues

Ashish K Tiwari @ashishktwari

Mumbai: That many depressed Americans tap India's yoga, Vedanta, mysticism and spirituality for peace of mind is well-known. Now India has an additional offering, a modern one at that, for such people.

Five Indian pharmaceuticals companies - Aurbindo Pharma, Dr Reddy's Laboratories, Lupin, Sun Pharma and Torrent - and Israel's Teva have received the US Food and Drug Administration (FDA) permission to market generic versions of blockbuster antidepressant drug Cymbalta.

American drug MNC Eli Lilly's patent over Cymbalta expired on Wednesday. The six companies will share the 180-day marketing exclusivity period.

Lupin's US subsidiary, which has also received FDA nod for three other drugs, has already launched Cymbalta's generic version of the capsules in 20mg, 30mg and 60mg strengths.

The other three Lupin drugs are Trilipix (fenofibric acid delayed-release capsules), Trizivir and Zidovudine (used for the treatment of HIV-1 infections).

According to industry data, Cymbalta had annual US sales of \$5.43 billion and is one of the largest selling products globally.

Industry analysts said the five Indian pharma majors may notch up collective sales of around \$120-180 million for Cymbalta during the 180-day exclusivity period that began on Thursday.

Analysts also said Cymbalta generics will likely be

CHASING MEGA DOLLARS



Aurbindo, Dr Reddy's, Lupin, Sun Pharma and Torrent get 180-day exclusivity

One of the largest-selling products globally, Cymbalta's US sales touched \$5.43 billion last year

American drug MNC Eli Lilly's patent over Cymbalta expired on Wednesday

Indian pharma majors may notch up collective sales of around \$120-180 million during exclusivity

The drug is prescribed for the treatment of major depressive disorder, generalised anxiety disorder and diabetic peripheral neuropathic pain

launched at competitive prices, potentially destroying 85-90% of the value of Eli Lilly's patented drug.

"Assuming Lupin garners, say, 15-20% market share, sales during the first six months could be around \$30 million, and gross margins could be about 65% or \$15-18 million," said an analyst from an international brokerage.

Also known as duloxetine hydrochloride delayed-release capsules, the drug is prescribed for the treatment of major depressive disorder, generalised anxiety disorder and diabetic peripheral neuropathic pain.

Kathleen Uhl, acting director of the office of generic drugs in the US FDA's Centre for Drug Evaluation and Research, was quoted in a release as saying, "Healthcare professionals and consumers can be assured that these FDA-approved generic drugs have met our rigorous standards."

According to a Lupin spokesperson, the company has already launched Trilipix in overseas markets and has a 180-day marketing exclusivity for Trizivir.

The three products represent a total market size of \$6 billion making them highly lucrative. "Lupin has already launched two of these (the generics for Trilipix and Cymbalta) and the same could mean an upside for the company's revenues immediately," said the spokesperson.

Regular