**November 3, 2012**

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| --- | --- | --- | --- | --- |
| **Drug Name** | **Active Ingredient** | **Dosage Form/Route** | **Sponsor** | **Submission Type** |
| [Salonpas](http://links.govdelivery.com/track?type=click&enid=ZWFzPTEmbWFpbGluZ2lkPTIwMTIxMTA2LjExNzkwNTIxJm1lc3NhZ2VpZD1NREItUFJELUJVTC0yMDEyMTEwNi4xMTc5MDUyMSZkYXRhYmFzZWlkPTEwMDEmc2VyaWFsPTE2OTgwODQ0JmVtYWlsaWQ9cmVzZWFyY2hAcGhhcm1leGNpbC5jb20mdXNlcmlkPXJlc2VhcmNoQHBoYXJtZXhjaWwuY29tJmZsPSZleHRyYT1NdWx0aXZhcmlhdGVJZD0mJiY=&&&110&&&http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?SearchType=BasicSearch&fuseaction=Search.SearchAction&searchTerm=022029&source=govdelivery) | menthol; methyl salicylate | Patch; Topical | Hisamitsu | Efficacy Supplement with Clinical Data to Support |

**November 2, 2012**

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| --- | --- | --- | --- | --- |
| **Drug Name** | **Active Ingredient** | **Dosage Form/Route** | **Sponsor** | **Submission Type** |
| [Arava](http://links.govdelivery.com/track?type=click&enid=ZWFzPTEmbWFpbGluZ2lkPTIwMTIxMTA2LjExNzkwNTIxJm1lc3NhZ2VpZD1NREItUFJELUJVTC0yMDEyMTEwNi4xMTc5MDUyMSZkYXRhYmFzZWlkPTEwMDEmc2VyaWFsPTE2OTgwODQ0JmVtYWlsaWQ9cmVzZWFyY2hAcGhhcm1leGNpbC5jb20mdXNlcmlkPXJlc2VhcmNoQHBoYXJtZXhjaWwuY29tJmZsPSZleHRyYT1NdWx0aXZhcmlhdGVJZD0mJiY=&&&111&&&http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?SearchType=BasicSearch&fuseaction=Search.SearchAction&searchTerm=020905&source=govdelivery) | leflunomide | Tablet; Oral | Sanofi Aventis Us | Labeling Revision |
| [Nplate](http://links.govdelivery.com/track?type=click&enid=ZWFzPTEmbWFpbGluZ2lkPTIwMTIxMTA2LjExNzkwNTIxJm1lc3NhZ2VpZD1NREItUFJELUJVTC0yMDEyMTEwNi4xMTc5MDUyMSZkYXRhYmFzZWlkPTEwMDEmc2VyaWFsPTE2OTgwODQ0JmVtYWlsaWQ9cmVzZWFyY2hAcGhhcm1leGNpbC5jb20mdXNlcmlkPXJlc2VhcmNoQHBoYXJtZXhjaWwuY29tJmZsPSZleHRyYT1NdWx0aXZhcmlhdGVJZD0mJiY=&&&112&&&http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?SearchType=BasicSearch&fuseaction=Search.SearchAction&searchTerm=125268&source=govdelivery) | romiplostim | Injectable; Subcutaneous | Amgen | Labeling Revision |
| [Olanzapine and Fluoxetine Hydrochloride](http://links.govdelivery.com/track?type=click&enid=ZWFzPTEmbWFpbGluZ2lkPTIwMTIxMTA2LjExNzkwNTIxJm1lc3NhZ2VpZD1NREItUFJELUJVTC0yMDEyMTEwNi4xMTc5MDUyMSZkYXRhYmFzZWlkPTEwMDEmc2VyaWFsPTE2OTgwODQ0JmVtYWlsaWQ9cmVzZWFyY2hAcGhhcm1leGNpbC5jb20mdXNlcmlkPXJlc2VhcmNoQHBoYXJtZXhjaWwuY29tJmZsPSZleHRyYT1NdWx0aXZhcmlhdGVJZD0mJiY=&&&113&&&http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?SearchType=BasicSearch&fuseaction=Search.SearchAction&searchTerm=077742&source=govdelivery) | fluoxetine hydrochloride; olanzapine | Capsule; Oral | Par Pharm | Approval |
| [Palonosetron Hydrochloride](http://links.govdelivery.com/track?type=click&enid=ZWFzPTEmbWFpbGluZ2lkPTIwMTIxMTA2LjExNzkwNTIxJm1lc3NhZ2VpZD1NREItUFJELUJVTC0yMDEyMTEwNi4xMTc5MDUyMSZkYXRhYmFzZWlkPTEwMDEmc2VyaWFsPTE2OTgwODQ0JmVtYWlsaWQ9cmVzZWFyY2hAcGhhcm1leGNpbC5jb20mdXNlcmlkPXJlc2VhcmNoQHBoYXJtZXhjaWwuY29tJmZsPSZleHRyYT1NdWx0aXZhcmlhdGVJZD0mJiY=&&&114&&&http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?SearchType=BasicSearch&fuseaction=Search.SearchAction&searchTerm=203050&source=govdelivery) | palonosetron hydrochloride | Injectable; Injection | Dr Reddys Labs Ltd | Tentative Approval |
| [Pradaxa](http://links.govdelivery.com/track?type=click&enid=ZWFzPTEmbWFpbGluZ2lkPTIwMTIxMTA2LjExNzkwNTIxJm1lc3NhZ2VpZD1NREItUFJELUJVTC0yMDEyMTEwNi4xMTc5MDUyMSZkYXRhYmFzZWlkPTEwMDEmc2VyaWFsPTE2OTgwODQ0JmVtYWlsaWQ9cmVzZWFyY2hAcGhhcm1leGNpbC5jb20mdXNlcmlkPXJlc2VhcmNoQHBoYXJtZXhjaWwuY29tJmZsPSZleHRyYT1NdWx0aXZhcmlhdGVJZD0mJiY=&&&115&&&http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?SearchType=BasicSearch&fuseaction=Search.SearchAction&searchTerm=022512&source=govdelivery) | dabigatran etexilate mesylate | Capsule; Oral | Boehringer Ingelheim | Labeling Revision |
| [Victrelis](http://links.govdelivery.com/track?type=click&enid=ZWFzPTEmbWFpbGluZ2lkPTIwMTIxMTA2LjExNzkwNTIxJm1lc3NhZ2VpZD1NREItUFJELUJVTC0yMDEyMTEwNi4xMTc5MDUyMSZkYXRhYmFzZWlkPTEwMDEmc2VyaWFsPTE2OTgwODQ0JmVtYWlsaWQ9cmVzZWFyY2hAcGhhcm1leGNpbC5jb20mdXNlcmlkPXJlc2VhcmNoQHBoYXJtZXhjaWwuY29tJmZsPSZleHRyYT1NdWx0aXZhcmlhdGVJZD0mJiY=&&&116&&&http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?SearchType=BasicSearch&fuseaction=Search.SearchAction&searchTerm=202258&source=govdelivery) | boceprevir | Capsule; Oral | Merck Sharp Dohme | Labeling Revision |
| [Xarelto](http://links.govdelivery.com/track?type=click&enid=ZWFzPTEmbWFpbGluZ2lkPTIwMTIxMTA2LjExNzkwNTIxJm1lc3NhZ2VpZD1NREItUFJELUJVTC0yMDEyMTEwNi4xMTc5MDUyMSZkYXRhYmFzZWlkPTEwMDEmc2VyaWFsPTE2OTgwODQ0JmVtYWlsaWQ9cmVzZWFyY2hAcGhhcm1leGNpbC5jb20mdXNlcmlkPXJlc2VhcmNoQHBoYXJtZXhjaWwuY29tJmZsPSZleHRyYT1NdWx0aXZhcmlhdGVJZD0mJiY=&&&117&&&http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?SearchType=BasicSearch&fuseaction=Search.SearchAction&searchTerm=022406&source=govdelivery) | rivaroxaban | Tablet; Oral | Janssen Pharms | Efficacy Supplement with Clinical Data to Support |
| [Zithromax](http://links.govdelivery.com/track?type=click&enid=ZWFzPTEmbWFpbGluZ2lkPTIwMTIxMTA2LjExNzkwNTIxJm1lc3NhZ2VpZD1NREItUFJELUJVTC0yMDEyMTEwNi4xMTc5MDUyMSZkYXRhYmFzZWlkPTEwMDEmc2VyaWFsPTE2OTgwODQ0JmVtYWlsaWQ9cmVzZWFyY2hAcGhhcm1leGNpbC5jb20mdXNlcmlkPXJlc2VhcmNoQHBoYXJtZXhjaWwuY29tJmZsPSZleHRyYT1NdWx0aXZhcmlhdGVJZD0mJiY=&&&118&&&http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?SearchType=BasicSearch&fuseaction=Search.SearchAction&searchTerm=050693&source=govdelivery) | azithromycin | For Suspension; Oral | Pfizer | Labeling Revision |
| [Zithromax](http://links.govdelivery.com/track?type=click&enid=ZWFzPTEmbWFpbGluZ2lkPTIwMTIxMTA2LjExNzkwNTIxJm1lc3NhZ2VpZD1NREItUFJELUJVTC0yMDEyMTEwNi4xMTc5MDUyMSZkYXRhYmFzZWlkPTEwMDEmc2VyaWFsPTE2OTgwODQ0JmVtYWlsaWQ9cmVzZWFyY2hAcGhhcm1leGNpbC5jb20mdXNlcmlkPXJlc2VhcmNoQHBoYXJtZXhjaWwuY29tJmZsPSZleHRyYT1NdWx0aXZhcmlhdGVJZD0mJiY=&&&119&&&http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?SearchType=BasicSearch&fuseaction=Search.SearchAction&searchTerm=050710&source=govdelivery) | azithromycin | For Suspension; Oral | Pfizer | Labeling Revision |
| [Zithromax](http://links.govdelivery.com/track?type=click&enid=ZWFzPTEmbWFpbGluZ2lkPTIwMTIxMTA2LjExNzkwNTIxJm1lc3NhZ2VpZD1NREItUFJELUJVTC0yMDEyMTEwNi4xMTc5MDUyMSZkYXRhYmFzZWlkPTEwMDEmc2VyaWFsPTE2OTgwODQ0JmVtYWlsaWQ9cmVzZWFyY2hAcGhhcm1leGNpbC5jb20mdXNlcmlkPXJlc2VhcmNoQHBoYXJtZXhjaWwuY29tJmZsPSZleHRyYT1NdWx0aXZhcmlhdGVJZD0mJiY=&&&120&&&http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?SearchType=BasicSearch&fuseaction=Search.SearchAction&searchTerm=050711&source=govdelivery) | azithromycin | Tablet; Oral | Pfizer | Labeling Revision |
| [Zithromax](http://links.govdelivery.com/track?type=click&enid=ZWFzPTEmbWFpbGluZ2lkPTIwMTIxMTA2LjExNzkwNTIxJm1lc3NhZ2VpZD1NREItUFJELUJVTC0yMDEyMTEwNi4xMTc5MDUyMSZkYXRhYmFzZWlkPTEwMDEmc2VyaWFsPTE2OTgwODQ0JmVtYWlsaWQ9cmVzZWFyY2hAcGhhcm1leGNpbC5jb20mdXNlcmlkPXJlc2VhcmNoQHBoYXJtZXhjaWwuY29tJmZsPSZleHRyYT1NdWx0aXZhcmlhdGVJZD0mJiY=&&&121&&&http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?SearchType=BasicSearch&fuseaction=Search.SearchAction&searchTerm=050730&source=govdelivery) | azithromycin | Tablet; Oral | Pfizer | Labeling Revision |
| [Zithromax](http://links.govdelivery.com/track?type=click&enid=ZWFzPTEmbWFpbGluZ2lkPTIwMTIxMTA2LjExNzkwNTIxJm1lc3NhZ2VpZD1NREItUFJELUJVTC0yMDEyMTEwNi4xMTc5MDUyMSZkYXRhYmFzZWlkPTEwMDEmc2VyaWFsPTE2OTgwODQ0JmVtYWlsaWQ9cmVzZWFyY2hAcGhhcm1leGNpbC5jb20mdXNlcmlkPXJlc2VhcmNoQHBoYXJtZXhjaWwuY29tJmZsPSZleHRyYT1NdWx0aXZhcmlhdGVJZD0mJiY=&&&122&&&http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?SearchType=BasicSearch&fuseaction=Search.SearchAction&searchTerm=050784&source=govdelivery) | azithromycin | Tablet; Oral | Pfizer | Labeling Revision |