

From: s22
To: SAS
Cc: s22
Subject: Update report [SEC=No Protective Marking]
Date: Sunday, 27 August 2017 10:27:04 PM
Attachments: [2017-08-29 SAS report 21Aug2017.pdf](#)

Dear Sir or Madam:

Please find our ongoing report re the subjects treated under the SAS program with the drug Pentosan Polysulfate Sodium.

Should you require any additional information please contact me on my mobile phone or email as outlined in my signature below.

Kind regards,

s22

[Redacted]

[Redacted]

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24 August 2017

Special Access Scheme
Pharmacovigilance and Special Access Branch
Therapeutic Goods Administration
PO Box 100
Woden ACT 2606
Australia
By email: SAS@health.gov.au

Dear TGA

Re: Report on usage of pentosan polysulfate sodium (PPS) under the Special Access Scheme

Please find attached a report for usage of PPS 100 mg/mL injection under the Special Access Scheme for the period 23 February 2017 to 23 August 2017.

Paradigm has supplied PPS for use in 15 patients as shown in details on pages 2 and 3. One adverse reaction has been reported.

Please contact me if you would like further clarification.

Yours sincerely

s22

Paradigm Biopharmaceuticals Ltd

phone: s22

email: s22

Usage of pentosan polysulfate sodium under the Special Access Scheme

Reporting period: 23 February 2017 to 23 August 2017

SAS approval number	Dosage regimen Dose/frequency/ duration)	Date commenced (DDMMYY)	Date completed (DDMMYY)	Number of ampoules issued	Number of ampoules returned	Adverse reactions reported (Y/N) If yes provide ADR number
2017/02551	2mg/kg Twice a week for 3 weeks	16-Mar-17	31-Mar-17	20	Destroyed at clinic	No
2017/03054	2mg/kg Twice a week for 3 weeks	14-Mar-17	30-Mar-17	20	Destroyed at clinic	No
2017/03427	2mg/kg Twice a week for 3 weeks	24-Apr-17	11-May-17	20	Destroyed at clinic	No
2017/05181	2mg/kg Twice a week for 3 weeks	24-Apr-17	11-May-17	20	Destroyed at clinic	No
2017/05180	2mg/kg Twice a week for 3 weeks	08-May-17	25-May-17	20	Destroyed at clinic	No
2017/06386	2mg/kg Twice a week for 3 weeks	04-May-17	22-May-17	20	Destroyed at clinic	No
2017/07032	2mg/kg Twice a week for 3 weeks	22-May-17	08-Jun-17	20	Destroyed at clinic	No
2017/07033	2mg/kg Twice a week for 3 weeks	22-May-17	08-Jun-17	20	Destroyed at clinic	No
2017/07149	2mg/kg Twice a week for 3 weeks	18-Jul-17	04-Aug-17	20	Destroyed at clinic	No

2017/07221	2mg/kg Twice a week for 3 weeks	22-Jun-17	10-Jul-17	20	Destroyed at clinic	No
2017/08827	2mg/kg Twice a week for 3 weeks	26-Jun-17	13-Jul-17	20	Destroyed at clinic	No
2017/09889	2mg/kg Twice a week for 3 weeks	06-Jul-17	24-Jul-17	20	Destroyed at clinic	No
2017/11278	2mg/kg Twice a week for 3 weeks	08-Aug-17	25-Aug-17	20	Destroyed at clinic	No
2017/08109	2mg/kg Twice a week for 3 weeks	06-Jun-17	23-Jun-17	20	Destroyed at clinic	No
2017/03081	2mg/kg Twice a week for 6 weeks	07-Apr-17	23-Apr-17	30	Destroyed at clinic	Yes, ADR No. 414073