

Single Antigen Vaccines Initiative (SAVI): Parents' Copy

Please read and retain this sheet for your records. Fill the enclosed Clinic Copy and send to the address below.

We would like to welcome you to the services and information offered by Direct Remedies Ltd. We manage the child-health clinic run by Dr. D. D. Ratnasinghe as part of his private practice. He is a consultant paediatrician working in the NHS. It must be emphasised that this service is offered by him in a private capacity and is in no way connected to or supported by the NHS. All the clinical processes and procedures at Direct Remedies Ltd are under his direct supervision. Dr. Ratnasinghe is registered as a specialist paediatrician and regulated by the General Medical Council. He is also registered as the data protection officer for these clinics under the Data Protection Act. He holds insurance cover through the Medical Defence Union. His high standards of personalised service, attention to detail and belief in enabling informed choices, have shaped the quality of our care pathways. Because he is not an independent medical practitioner that is wholly private, but is working for the NHS in a substantive capacity, his private practice cannot be registered with the Care Quality Commission.

Logistic support to the clinics is provided by Direct Remedies Limited: a management consulting, marketing and healthcare company. Direct Remedies Limited is registered in England and Wales and considers it a privilege to be associated as agents supporting this service. The company holds public liability and employer's liability insurance.

Vaccinations have proven invaluable over the decades in preventing the onset or reducing the severity of many serious or fatal illnesses. As you consider vaccinating your child against measles, mumps and rubella by single antigen injections rather than the combined MMR, there are a number of things to understand before finally giving consent.

- **Autism and bowel disease:** The causes of autism or inflammatory bowel disease (e.g. Crohns Disease) have not yet been fully elucidated. By offering the single antigen vaccination course, we are not implying that there is any proven link with these conditions and the combined MMR vaccine. We do not know of any guaranteed way to prevent these devastating illnesses.
- **Licences:** The Medicines and Healthcare products Regulatory Agency (MHRA) is a division of the Department of Health (DoH). It is responsible for issuing licenses for the manufacture and sale of drugs/vaccines as well as licensing the importation of drugs/vaccines to the UK. After the introduction of the MMR, the single measles vaccine lost its demand in the UK and manufacturers allowed the relevant licenses to expire probably because it was no longer commercially viable. It was **not** withdrawn for safety concerns. Meanwhile manufacturers continue to make and market the vaccine in Europe, USA and other countries. The single rubella vaccine still had a place in vaccinating non-immune mothers and carried on being marketed and available in the UK until 2002 when that too ceased, apparently due to commercial reasons. The single antigen mumps vaccine was initially used widely in the USA in the 1980s but was never introduced into the UK vaccination programme. It was combined with measles and rubella and introduced altogether, within the MMR. None of the brands of single antigen vaccines described below are licensed for manufacture or sale in the UK but are licensed for importation into the UK by the MHRA.
- **Supply problems: The vaccinations are subject to availability.** We have no control over the vaccine quantities that are manufactured or available for importation into the UK. As a result, there are occasions when the supplies run out. Please enquire about availability and ensure that you obtain the most important Measles vaccine first.
- **Measles Vaccine:** There are two vaccine brands currently used by our clinics. They are manufactured in the EU and India, under appropriate licenses in their home countries. The brands are Rouvax (Schwarz Strain), SII (Edmonston-Zagreb Strain).
- **Mumps Vaccine:** The most reliable strain of mumps vaccine is called Jeryl Lynn. A derivative of this strain is contained in the MMR. We have used the single mumps brand called Mumpsvox which has this strain. Currently not available and alternatives are being sourced.
- **Rubella Vaccine:** All brands of the single rubella vaccine used by us (e.g. Rudivax, SII Rubella) contain the Wistar RA 27/3 strain of virus. This is the same strain contained in the MMR. Manufactured in the EU or India.
- **The Mercury Issue:** There have been increasing concerns about the mercury content of a number of widely used vaccine pro MMR3 stMercury is a constituent of a preservative called Thiomersal (or Thimerosal) which is added in some manufacturing processes. None of the single vaccines used in our clinics contain mercury in any form.

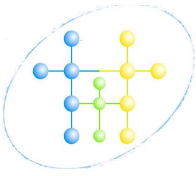
- **Risks:** All three vaccines are live and may produce a high temperature, general aches, rashes, runny nose or swollen glands: for a few days, soon after the injection or 7 to 21 days later when the vaccine is exerting its effects. Some very rare side effects have been seen over the decades of vaccine use. They include local swelling and redness, inflamed joints, inflammatory damage to the nervous system, the full blown disease itself and alterations in the blood cell counts. We cannot guarantee that any vaccine is absolutely safe with no side effects whatsoever. For more details please ask at your consultation. The single vaccine course is slower than the combined MMR because of the gaps between each vaccine and possible delays or scarcities in vaccine supply.
- **Benefits and effectiveness:** The vaccines we offer have a proven track record at stimulating the immune system to produce antibodies that will protect against the relevant disease occurring or being severe. Due to individual variations in the immune system from person to person, the overall rate of antibody production is around 90% to 95%. Rates for the combined MMR are similar or indeed lower. It is important to obtain all three vaccines and not omit the rubella or mumps under the impression that they are not severe illnesses for boys or girls etc. Rubella is devastating to foetuses. Mumps can cause rare complications such as encephalitis and sterility (the latter in boys after puberty). It is important to consider seeking booster doses at appropriate intervals.
- **Infection from the vaccine to others:** Please note that the vaccine strain of virus is not infectious. It will therefore not pose a risk to pregnant mothers or to individuals with a lowered immunity if they come in to contact with your child.
- **Storage and transport:** As recommended by the manufacturers, the storage and transport of the vaccines is such that they are always kept between 2 and 8 degrees centigrade. Industry standard fridges, cool boxes and ice packs are used for this purpose in order to maintain the essential cold chain.
- **Preparing vaccine for injection:** The virus is contained in the form of a pellet in a vial and is supplied with fluid to mix it with. The two components get mixed immediately prior to injecting the solution into your child as recommended by the manufacturers.
- **Antibody profile testing:** Measuring the amount of antibodies in the blood is a way of assessing the immunity conferred by the vaccines. The test is not always accurate and it cannot predict the future immune status. It should not replace obtaining boosters.
- **The vaccination course:** There is no compulsory order in which the vaccines should be given but Measles vaccines should be obtained first whenever possible. The minimum age for these vaccines is 12 months, there is no upper age limit. The gap is a minimum of 6 weeks between each vaccine, in order to ensure the body has recovered from the previous vaccine and not leave it unnecessarily long before the next one. You are however free to keep a longer gap if you prefer.
- **Clinical supervision and aftercare:** Dr. Ratnasinghe, Consultant Paediatrician, personally ensures that all the above procedures and processes are maintained according to his high standards and strong commitment. He provides 24 hour support to address any concerns after the vaccines have been administered: on 07974 383 471.

Prices are subject to change without notice. Vaccinations are subject to availability. Please call 0845 130 4595 to confirm current rates and availability. There is a £105 fee (£85 if already registered) applicable to the Single Antigen Vaccines Initiative (SAVI) at registration which includes a registration fee of £20. Bookings will be confirmed on receipt of this fee.

What to do now:

1. Contact us on 0845 130 4595 or jab@directremedies.com for more details if required
2. Read all the information above carefully and fill the enclosed Application Form as fully as you can. Leave the last page blank for it to be completed during each vaccination visit.
3. Sign the Authorisation section thus allowing us to process the application and order the vaccines for your child.
4. Post the completed form with a cheque for the fee made payable to Direct Remedies Ltd to Direct Remedies, 31 Harewood Road, Isleworth, Middlesex, TW7 5HB.
5. Please bring your child's personal health record (**Red/Yellow/Blue or Green book**) for the vaccination appointment.
6. If any additional outreach or appointment information is required (e.g. venues and times) please contact us directly via 0845 130 4595.

PLEASE RETAIN THIS COPY FOR YOUR INFORMATION AND RECORDS.



Single Antigen Vaccines Initiative (SAVI): Clinic Copy

Single Antigen Vaccines Initiative (SAVI): Application and Authorisation Form

(Please fill this two page form, sign the authorisation at the end and return to the address below with your registration fee/vaccine fee. Leave the last page blank to be filled and signed for consent during each clinic visit)

There may be a £10 discretionary charge for any cancellation of appointments within 24 hours.

Parent / Guardian Details: Surname: Mr / Mrs / Miss* _____

First Name(s): _____ Tel: Landline: _____ Mobile: _____

Address: _____

_____. Postcode: _____ E-mail: _____

Child for Vaccinations: Details: Surname: _____

First Name(s): _____ Date of Birth: _____ Male / Female*

GP Details: If you would like us to inform your family doctor of the vaccinations your child has received, please supply:

Name of Doctor : _____ Tel No.: _____

Address: _____

_____. Post Code: _____

Child's Vaccination History: What vaccinations has your child already had? (Please circle)

Diphtheria (DIP) / Tetanus (TET)/ Whooping Cough (PER) / HIB / BCG / Polio / Men C / Other _____

Single Rubella / Single Measles / Single Mumps

Did he/she receive the first combined MMR? Yes / No* If yes, any complications: _____

Family Medical History: Do any of the following illnesses occur in the family? (Please circle)

NONE / Diabetes / Asthma / Crohns / Other bowel disease / Thyroid disease / Cancers / Eczema / Severe allergies

Aspergers / Autism / ADHD / Behavioural disorders / Blood disorders. / Rheumatological disease / Others _____

How is your child related to the relevant person/people above?

Child's Health Record.

Were there any problems during pregnancy? Yes / No*. If yes, details: _____

Was he/she born premature? Yes / No*. If yes, number of weeks: _____ Birth Weight: _____

Any complications: _____

Have any of the following occurred in the past or present? (Please circle) Eczema / Crohns / Other bowel disease / Aspergers / Autism / ADHD / Diabetes / Asthma / Thyroid disease / Blood disorder / Malignancy (cancer) / **Other / NONE.**

Any other illnesses or surgical operations? Yes / No*. If yes, details: _____

What is his/her current general health? _____

Any current medications? Yes / No*. If yes, details: _____

Any known allergies? Yes / No*. If yes, details: _____

Clinic Venue / Location: Please indicate the name of the clinic venue or location you wish to attend.

BMI Syon Clinic (London) __ Brighton Clinic __ Glasgow Clinic __ Newcastle Clinic __ York Clinic __ Bristol Clinic __

Manchester Clinic __ Peterborough Clinic __ Exeter Clinic __ Other Clinic __

Authorisation and Confirmation: (Signing this section gives us permission to process your application fully)

I authorise Dr.D.D.Ratnasinghe to safeguard and store my / our records in paper and electronic form (Please note that the information will only be used to organise safe and smooth vaccination sessions for your child and to conduct internal audits as necessary: all in accordance with the Data Protection Act). Yes / No*

I confirm that Dr.D.D.Ratnasinghe may import the vaccines on my child's behalf in accordance with the relevant approved processes. Yes / No*

I understand that I retain the right to withdraw my child from the Single Antigen Vaccines Initiative (SAVI) at any time but there will be a charge incurred. Yes / No*

Signature of Parent / Guardian: _____ Date: _____

Yours Reasons (Optional): Finally, please share with us your reasons for choosing the single vaccines as an alternative to the combined MMR.

Note: Please send this application form with your registration fee/vaccine fee (by cheque made payable to 'Direct Remedies Ltd') to

Direct Remedies Ltd, 31 Harewood Road, Isleworth, Middlesex. TW7 5HB

The next page is to be filled in during each vaccine consultation and includes consent for each vaccination.

CLINIC USE ONLY

Name of Child: _____ Date of Birth _____

1st Vaccine: Measles / Mumps / Rubella. Date: _____ Location: _____
Brand Name: _____ Lot/Batch no: _____ Exp Date: _____
Fit for Vaccination Yes / No*. Site of Injection: _____

I am the parent / legal guardian of the above-named child and confirm that all relevant information about the vaccination has been given to me and fully understood by me. I have been given the opportunity to consider the decision and ask any further questions from the doctor or nurse as necessary. **I do consent to my child receiving the above vaccine.**

Name: _____ Signature: _____ Date: _____

I Dr/Mr/Ms: _____ hereby declare that the above is a true reflection of the informed consent process. All relevant information and outstanding questions have been addressed.

Signature of doctor / nurse: _____ Date: _____

2nd Vaccine: Measles / Mumps / Rubella. Date: _____ Location: _____
Brand Name: _____ Lot/Batch no: _____ Exp Date: _____
Fit for Vaccination Yes / No*. Site of Injection: _____

I am the parent / legal guardian of the above-named child and confirm that all relevant information about the vaccination has been given to me and fully understood by me. I have been given the opportunity to consider the decision and ask any further questions from the doctor or nurse as necessary. **I do consent to my child receiving the above vaccine.**

Name: _____ Signature: _____ Date: _____

I Dr/Mr/Ms: _____ hereby declare that the above is a true reflection of the informed consent process. All relevant information and outstanding questions have been addressed.

Signature of doctor / nurse: _____ Date: _____

3rd Vaccine: Measles / Mumps / Rubella. Date: _____ Location: _____
Brand Name: _____ Lot/Batch no: _____ Exp Date: _____
Fit for Vaccination Yes / No*. Site of Injection: _____

I am the parent / legal guardian of the above-named child and confirm that all relevant information about the vaccination has been given to me and fully understood by me. I have been given the opportunity to consider the decision and ask any further questions from the doctor or nurse as necessary. **I do consent to my child receiving the above vaccine.**

Name: _____ Signature: _____ Date: _____

I Dr/Mr/Ms: _____ hereby declare that the above is a true reflection of the informed consent process. All relevant information and outstanding questions have been addressed.

Signature of doctor / nurse: _____ Date: _____